

10 Friday, February 8, 2019

11 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
12 CONFIDENTIALITY REVIEW

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	Page 2	Page 4
1 A P P E A R A N C E S:		
2 KELLER ROHRBACK LLP	1 INDEX	
3 BY: ERIKA M. KEECH, ESQUIRE	2	
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5 1201 3rd Avenue, Suite 3200	4	
6 Seattle, Washington 98101-3052	5 EXAMINATION OF GEORGE SAFFOLD:	
7 (202) 623-1900	6 QUESTIONS BY MS. KEECH.....12	
8 Counsel for Plaintiffs	7 QUESTIONS BY MR. GASTEL.....196	
9 KELLER ROHRBACK LLP	8	
10 BY: GARY GOTTO, ESQUIRE	9	
11 ggetto@kellerrohrback.com	10	
12 3101 North Central Avenue	11 CERTIFICATE	249
13 Suite 1400	12 LAWYER'S NOTES	250
14 Phoenix, Arizona 85012-2600	13	
15 (602) 248-0088	14 Index of Media	
16 Counsel for Plaintiffs	15 File 1	10
17 BRANSTETTER, STRANCH & JENNINGS, PLLC	16 File 2	94
18 BY: BENJAMIN A. GASTEL, ESQUIRE	17 File 3	169
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20 SpecGx LLC and The Witness		
21 A P P E A R A N C E S, Continued:	Page 3	Page 5
22 JONES DAY		
23 BY: LAURA JANE DURFEE, ESQUIRE	1 E X H I B I T I N D E X	
24 ldurfee@jonesday.com	2 Description	
25 2727 North Harwood Street	3 Plaintiffs' Notice of	14
1 Dallas, Texas 75201-1515	4 Saffold Oral Videotaped	
2 (214) 220-3939	5 Exhibit 1 Deposition of George	
3 Counsel for Walmart	6 Saffold and Requests for	
4 REED SMITH LLP	7 Production of Documents	
5 BY: MARY BALASTER, ESQUIRE	8 Mallinckrodt- Covidien Letter to	
6 mbalaster@reedsmith.com	9 Saffold George Saffold dated	39
7 811 Main Street, Suite 1700	10 Exhibit 2 January 21, 2013	
8 Houston, Texas 77002	11 MNK-T1_0007219867 -	
9 (713) 469-3800	12 7219673 -	
10 Counsel for AmerisourceBergen Drug	13 Mallinckrodt- E-mail Chain ending with	58
11 Corporation	14 Saffold E-mail from Borelli,	
12 COVINGTON & BURLING LLP	15 Exhibit 3 July 29, 2009	
13 BY: ALEXANDRA J. WIDAS, ESQUIRE	16 MNK-T1_0000290150 -	
14 awidas@cov.com	17 290151	
15 (via teleconference)	18 Mallinckrodt- E-mail Chain ending with	62
16 One City Center	19 Saffold E-mail from Harper,	
17 850 Tenth Street, N.W.	20 Exhibit 4 10/31/2009	
18 Washington, D.C. 20001	21 MNK-T1_0007179935 -	
19 (202) 662-6000	22 179936	
20 Counsel for McKesson Corporation	23 Mallinckrodt- E-mail Chain ending with	69
21 ARNOLD & PORTER KAYE SCHOLER LLP	24 Saffold E-mail from Stewart,	
22 BY: JAKE R. MILLER, ESQUIRE	25 Exhibit 5 November 17, 2009	
23 jake.miller@arnoldporter.com	26 MNK-T1_0000263249 -	
24 (via teleconference)	27 263250	
25 777 South Figueroa Street, 44th Floor	28 Mallinckrodt- E-mail from Saffold to	73
1 Los Angeles, California 90017-5844	29 Saffold Rausch, 11/30/2009	
2 (213) 243-4000	30 Exhibit 6 MNK-T1_0000302469	
3 Counsel for Endo Health Solutions	31 Mallinckrodt- E-mail from Saffold to	75
4 Inc., Endo Pharmaceuticals Inc., Par	32 Saffold Rausch, 12/22/2009	
5 Pharmaceutical, Inc. and Par	33 Exhibit 7 MNK-T1_0000303789	
6 Pharmaceutical Companies, Inc.	34 Mallinckrodt- E-mail Chain ending with	77
7 VIDEOGRAPHER:	35 Saffold E-mail from Harper,	
8 BRIAN BOBBITT, Golkow Litigation Services	36 Exhibit 8 January 19, 2010	
9	37 MNK-T1_0000263201	

		Page 6		Page 8		
1	Mallinckrodt- Saffold	Suspicious Order Monitoring Team Charter, Exhibit 9 Updated 04/07/11 MNK-T1_0000496062	79	1 Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Johnson to Exhibit 25 Saffold, 10/26/2011 MNK-T1_0005711355 - 5711356 -	153
2	Mallinckrodt- Saffold	Mallinckrodt Controlled Substance Suspicious Exhibit 10 Order Monitoring Program Presentation for Marketing Group, March 21, 2011 MNK-T1_0000496098 - 496124	82	3 Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Rausch to Exhibit 26 Banks, 10/27/2011 MNK-T1_0002742739 - 2742742 -	162
3	Mallinckrodt- Saffold	Memo to Saffold from Rausch, Subject: Exhibit 11 Pharmaceutical Logistics Monthly Report-June 2009 MNK-T1_0000303583 - 303585 -	95	4 Mallinckrodt- Saffold	E-mail from Cardetti to Collier, 11/4/2011 MNK-T1_0000299509	164
4	Mallinckrodt- Saffold	Interoffice Correspondence to Levy Exhibit 12 from Saffold, Subject: Customer Service Monthly Report-September 2009 MNK-T1_0000302318 - 302320 -	109	5 Mallinckrodt- Saffold	Knowledge Management System Questions Exhibit 28 Pharma, Pat Wall, 04-22-10 MNK-T1_0004595958 - 4595961 -	166
5	Mallinckrodt- Saffold	Memo to Santowski from Saffold dated November 2, 2010, Subject: October Monthly Report - Customer Service MNK-T1_0000280653 - 280654 -	112	6 Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Collier to Exhibit 29 Saffold, 8/12/2010 MNK-T1_0000368976 - 368977 -	169
6	Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Harper to Exhibit 14 Spaulding, March 12, 2010 MNK-T1_0000269705	115	7 Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Nelson to Exhibit 30 Saffold, 9/26/2011 MNK-T1_0000299364 - 299366 -	173
7	Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Rausch to Exhibit 15 Harper, June 9, 2010 MNK-T1_0000262762	117	8 Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Saffold to Exhibit 31 Santowski, 9/27/2011 MNK-T1_0003064400 - 3064401 -	175
8	Mallinckrodt- Saffold	Levy, 6/17/2010 MNK-T1_0000279164	118	9 Mallinckrodt- Saffold	E-mail from Harper to Exhibit 32 Levy, 6/17/2010 MNK-T1_0000279164	178
9	Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Saffold to Rehkop, 7/13/2011 MNK-T1_0000495396 - 495400	119	10 Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Saffold to Rehkop, 7/13/2011 MNK-T1_0000495396 - 495400	182
10	Mallinckrodt- Saffold	Meeting/Appointment Invitation, Subject: DEA Suspicious Order Monitoring Program, 7/30/2010 MNK-T1_0000268194	121	11 Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Harper to Exhibit 34 Becker, 7/13/2011 MNK-T1_0004604436 - 4604440 -	186
11	Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Rausch to Exhibit 17 Harper, June 9, 2010 MNK-T1_0000262763	124	12 Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Saffold to Exhibit 35 Rausch, 7/23/2012 MNK-T1_0004155087 - 4155092 -	189
12	Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Saffold to Harper, 11/3/2010 MNK-T1_0000280678	126	13 Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Harper to Exhibit 36 Levy, 9/15/2009 MNK-T1_0007823812 - 7823814 -	192
13	Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Ratliff to Exhibit 19 Harper, 11/18/2009 MNK-T1_0000301254 - 301256 -	128	14 Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Santowski to Exhibit 37 Saffold, 4/21/2011, with Attachment(s) MNK-T1_0007114309 - 7114310 -	205
14	Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Harper to Rausch, 11/6/2009 MNK-T1_0000278389 - 278390 -	129	15 Mallinckrodt- Saffold	E-mail from Buist to Gilles, 12/12/2012, with Attachment(s) MNK-T1_0006967774 - 6967777 -	216
15	Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Stewart to Exhibit 21 Harper, 11/6/2009 MNK-T1_0004154291	132	16 Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Bell to Longenecker, 10/8/2013 MNK-T1_0004291190 - 4291195 -	224
16	Mallinckrodt- Saffold	Meeting/Appointment Invitation from Harper, Exhibit 22 7/22/2010 MNK-T1_0000455782	136	17 Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Breneman to Saffold, 1/20/2017 MNK-T1NSTA04824847 - 4824854 -	231
17	Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Digby to Saffold, 5/30/2012 MNK-T1_0005708609	143	18 Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Martinez to Saffold, 10/28/2013, with Attachment(s) MNK-T1_0007872732 - 7872733 -	240
18	Mallinckrodt- Saffold	E-mail Chain ending with E-mail from Cardetti to Saffold, 10/27/2011 MNK-T1_0000299450 - 299453 -	147	19 Mallinckrodt- Saffold		
19	Mallinckrodt- Saffold		20	20 Mallinckrodt- Saffold		
20	Mallinckrodt- Saffold		21	21 Mallinckrodt- Saffold		
21	Mallinckrodt- Saffold		22	22 Mallinckrodt- Saffold		
22	Mallinckrodt- Saffold		23	23 Mallinckrodt- Saffold		
23	Mallinckrodt- Saffold		24	24 Mallinckrodt- Saffold		
24	Mallinckrodt- Saffold		25	25 Mallinckrodt- Saffold		

Page 10	Page 12
<p>1 (Friday, February 8, 2019, 9:08 a.m.)</p> <p>2 THE VIDEOGRAPHER: All right,</p> <p>3 stand by. We are now on the record.</p> <p>4 My name is Brian Bobbitt. I'm a</p> <p>5 videographer for Golkow Litigation</p> <p>6 Services. Today's date is February 8,</p> <p>7 2019. The time is 9:08 a.m.</p> <p>8 This video deposition is being</p> <p>9 held in Fort Worth, Texas, in the</p> <p>10 National Prescription Opiate MDL,</p> <p>11 2804, case number, for the United</p> <p>12 States District Court, Northern</p> <p>13 District of Ohio, Eastern Division.</p> <p>14 The deponent is George Saffold.</p> <p>15 Does counsel want to identify</p> <p>16 themselves for the record?</p> <p>17 MS. KEECH: Erika Keech from</p> <p>18 Keller Rohrback on behalf of the</p> <p>19 plaintiffs.</p> <p>20 MR. GOTTO: Gary Gotto from</p> <p>21 Keller Rohrback.</p> <p>22 MR. GASTEL: Ben Gastel from</p> <p>23 Branstetter Stranch & Jennings on</p> <p>24 behalf of the Tennessee plaintiffs.</p> <p>25 MS. DURFEE: Laura Jane Durfee</p>	<p>1 P R O C E E D I N G S</p> <p>2 GEORGE SAFFOLD,</p> <p>3 having taken an oath to tell the truth, the</p> <p>4 whole truth, and nothing but the truth,</p> <p>5 testified as follows:</p> <p>6 EXAMINATION</p> <p>7 QUESTIONS BY MS. KEECH:</p> <p>8 Q. Good morning. Can you please</p> <p>9 state and spell your name for the record?</p> <p>10 A. Yes. My name is George</p> <p>11 Saffold, G-E-O-R-G-E, S, as in Sam, A, F as</p> <p>12 in Frank, F as in Frank, O-L-D.</p> <p>13 Q. And where do you currently</p> <p>14 reside?</p> <p>15 A. In North Richland Hills, Texas.</p> <p>16 Q. Are you currently employed?</p> <p>17 A. Yes.</p> <p>18 Q. Where?</p> <p>19 A. For VF Corporation.</p> <p>20 Q. And where is VF located?</p> <p>21 A. My office is located in</p> <p>22 Fort Worth.</p> <p>23 Q. And you understand that you're</p> <p>24 under oath today, right?</p> <p>25 A. Yes.</p>
<p>1 from Jones Day for Walmart.</p> <p>2 MS. BALASTER: Mary Balaster</p> <p>3 with Reed Smith on behalf of</p> <p>4 AmerisourceBergen Drug Corporation.</p> <p>5 MS. LaRUSSA: Cassandra</p> <p>6 LaRusso, Ropes & Gray, on behalf of</p> <p>7 Mallinckrodt LLC, SpecGx and the</p> <p>8 witness.</p> <p>9 MR. BERG: Nick Berg from</p> <p>10 Ropes & Gray.</p> <p>11 MR. SAFFOLD: George Saffold.</p> <p>12 THE REPORTER: And those on the</p> <p>13 phone, please?</p> <p>14 MR. MILLER: Hi, this is Jake</p> <p>15 Miller from Arnold & Porter on behalf</p> <p>16 of the Endo and Par defendants.</p> <p>17 MS. WIDAS: Alexandra Widas</p> <p>18 from Covington & Burling on behalf of</p> <p>19 McKesson.</p> <p>20 (Witness sworn by the</p> <p>21 reporter.)</p> <p>22 (Examination begins on next</p> <p>23 page.)</p> <p>24 --oOo--</p> <p>25 --oOo--</p>	<p>1 Page 11</p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> <p>1 Q. Are you taking any medication</p> <p>2 or is there any other reason that would</p> <p>3 interfere with your ability to testify</p> <p>4 truthfully and fully today?</p> <p>5 A. No.</p> <p>6 Q. Okay. And if I ask a question</p> <p>7 you don't understand, please let me know and</p> <p>8 I will try and rephrase it.</p> <p>9 A. (Nods head.)</p> <p>10 Q. Have you ever testified in a</p> <p>11 deposition or trial before?</p> <p>12 A. No.</p> <p>13 Q. I'm sure your counsel explained</p> <p>14 some general rules, but I'll also go over</p> <p>15 some as well. The court reporter here has</p> <p>16 the important job of transcribing everything</p> <p>17 that we're saying to each other, so it's</p> <p>18 important that we don't talk over one</p> <p>19 another, and give audible answers.</p> <p>20 So, please, if I ask a</p> <p>21 yes-or-no question, rather than shaking your</p> <p>22 head, please answer yes or no. Does that</p> <p>23 sound good?</p> <p>24 A. Yes.</p> <p>25 Q. And are you represented by</p>

Page 14	Page 16
<p>1 counsel here today?</p> <p>2 A. Yes.</p> <p>3 Q. And who are they?</p> <p>4 A. They're from Ropes & Gray,</p> <p>5 Cassandra and Kevin.</p> <p>6 Q. Okay. From time to time, your</p> <p>7 counsel may object to questioning. Unless</p> <p>8 you get a clear instruction not to respond, I</p> <p>9 would ask that you respond to my question,</p> <p>10 okay?</p> <p>11 A. Yes.</p> <p>12 Q. And to the extent that you need</p> <p>13 a break, please let me know and I'll do my</p> <p>14 best to accommodate. I plan on taking breaks</p> <p>15 about every hour.</p> <p>16 A. Thank you.</p> <p>17 Q. Sir, I'm handing you what's</p> <p>18 been marked as Exhibit 1.</p> <p>19 (Mallinckrodt-Saffold Exhibit 1</p> <p>20 was marked for identification.)</p> <p>21 QUESTIONS BY MS. KEECH:</p> <p>22 Q. Do you recognize this document?</p> <p>23 A. Yes.</p> <p>24 Q. And what is it?</p> <p>25 A. It's a notice for the</p>	<p>1 A. No. I did not review my phone</p> <p>2 nor my personal computer.</p> <p>3 Q. Did anyone ask you to do that?</p> <p>4 A. Yes. I did not because</p> <p>5 they're -- I don't have any documents from</p> <p>6 Mallinckrodt on my personal computer, and I</p> <p>7 did not have a phone that I kept with me</p> <p>8 after I left Mallinckrodt.</p> <p>9 Q. And what did you do to prepare</p> <p>10 for this deposition today?</p> <p>11 A. I met with counsel on two</p> <p>12 separate occasions.</p> <p>13 Q. Did you review any deposition</p> <p>14 transcripts or complaints or other papers</p> <p>15 filed in this litigation?</p> <p>16 A. No.</p> <p>17 Q. And when you met with your</p> <p>18 attorneys, was it in person?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. And without telling me</p> <p>21 the content of your conversations, did you</p> <p>22 review documents with your attorneys?</p> <p>23 A. Yes.</p> <p>24 Q. And did reviewing documents</p> <p>25 refresh your recollection of any past events?</p>
Page 15	Page 17
<p>1 deposition today.</p> <p>2 Q. Okay. And when did you first</p> <p>3 see this document?</p> <p>4 A. Yesterday.</p> <p>5 Q. Would you turn with me to</p> <p>6 Schedule A? Do you see the request to bring</p> <p>7 documents?</p> <p>8 A. I'm sorry, can you give me a</p> <p>9 page? Oh, never mind. I do.</p> <p>10 Q. And did you search for</p> <p>11 documents that were responsive to this?</p> <p>12 A. Yes.</p> <p>13 Q. Did you look in your own</p> <p>14 personal paper or electronic files?</p> <p>15 A. Yes.</p> <p>16 Q. Did you ever use your personal</p> <p>17 e-mail to communicate with your work</p> <p>18 colleagues or customers about your work while</p> <p>19 you were employed with Mallinckrodt?</p> <p>20 A. No.</p> <p>21 Q. How about text messages?</p> <p>22 A. No.</p> <p>23 Q. Did you review your phone or</p> <p>24 personal computer for work-related text</p> <p>25 messages or e-mails?</p>	<p>1 A. Partially.</p> <p>2 Q. How so?</p> <p>3 A. The names of colleagues.</p> <p>4 Primarily that, just...</p> <p>5 Q. Did you speak with anyone else</p> <p>6 prior to this deposition, any former</p> <p>7 colleagues, friends still at the company?</p> <p>8 A. No.</p> <p>9 Q. And are you being reimbursed by</p> <p>10 anyone for your expenses in connection with</p> <p>11 this deposition?</p> <p>12 A. No.</p> <p>13 Q. Are you being compensated by</p> <p>14 anyone for your time in connection with your</p> <p>15 attendance or preparation for this</p> <p>16 deposition, including searching for your</p> <p>17 documents?</p> <p>18 A. No.</p> <p>19 Q. Did you graduate from college?</p> <p>20 A. Yes.</p> <p>21 Q. Where?</p> <p>22 A. Font Bonne University.</p> <p>23 Q. Can you spell that?</p> <p>24 A. F-O-N-T, B-O-N-N-E, University.</p> <p>25 Q. In what year?</p>

Page 18	Page 20
<p>1 A. 2016.</p> <p>2 Q. Can you briefly describe your 3 job history after high school to the present?</p> <p>4 A. Sure. After high school, I 5 worked in a variety of jobs, a lot of 6 restaurant jobs. I worked at Pasta House as 7 a restaurant bartender, cook and waiter. 8 It's where I met my future wife.</p> <p>9 From there, I worked at 10 Macaroni Grill as a bartender trainer. And 11 from there I became a development coordinator 12 for Macaroni Grill and ultimately for Brinker 13 International, which is the parent company of 14 Macaroni Grill, where I went on the road and 15 assisted with new unit development and 16 openings of new units.</p> <p>17 Following that role, I became a 18 temporary -- just kind of looking to make a 19 career change, so I became a temporary 20 employee with Manpower USA in data integrity; 21 and then I was assigned Mallinckrodt, and I 22 started working in data integrity at 23 Mallinckrodt.</p> <p>24 From there, I became a customer 25 service agent in our respiratory device</p>	<p>1 A. Yes. So I entered -- so it was 2 a temporary -- it was a very -- it was an 3 occupational job, so it had a lot of data 4 entry. Mallinckrodt had purchased a 5 respiratory company called Nellcor Puritan 6 Bennett, and there was an effort to put them 7 onto the same system as Mallinckrodt's 8 system.</p> <p>9 And when they translated the 10 addresses over, the -- not all the addresses. 11 Customer addresses looked great. So my job 12 was to go in and do things like retype an 13 attention line.</p> <p>14 And then also in that role, 15 about three hours a day I was assigned to 16 when a customer service rep entered a request 17 for a new customer address, my job was to 18 search to see if we actually already had that 19 address in our database.</p> <p>20 Q. Thank you. And what year did 21 you begin employment with Mallinckrodt?</p> <p>22 A. Around 1999.</p> <p>23 Q. And do you recall when you 24 transitioned to customer service?</p> <p>25 A. September of 1999, I believe.</p>
<p style="text-align: center;">Page 19</p> <p>1 division. Following that, I was a supervisor 2 of critical care customer service, which was 3 medical device.</p> <p>4 Following that, I was manager 5 of distributor logistics for Mallinckrodt on 6 the medical device side. Then I became 7 director -- oh, I'm sorry. Then I was 8 manager of distribution operations for 9 Mallinckrodt imaging and respiratory.</p> <p>10 Following that, I became director of customer 11 service for Mallinckrodt imaging solutions 12 and respiratory monitoring solutions.</p> <p>13 After that, I became director 14 of Mallinckrodt pharmaceutical and 15 respiratory. Then I became director of 16 Mallinckrodt pharmaceutical global customer 17 service. And then in March of 2017, I left 18 the company.</p> <p>19 Q. Thank you. Before joining 20 Mallinckrodt, did you have any experience in 21 the pharmaceutical industry?</p> <p>22 A. No.</p> <p>23 Q. Can you tell me a little bit 24 more about your role in data integrity? What 25 did that involve?</p>	<p style="text-align: center;">Page 21</p> <p>1 Q. So how long would you estimate 2 that you were in the data integrity group?</p> <p>3 A. Six-ish months.</p> <p>4 Q. Okay. Do you hold any 5 professional licenses or certificates?</p> <p>6 A. Yes.</p> <p>7 Q. And what are they?</p> <p>8 A. I'm a Six Sigma Business 9 Process Green Belt.</p> <p>10 Q. And where did you obtain that 11 certification?</p> <p>12 A. Tyco Healthcare.</p> <p>13 Q. Have you taken any courses 14 related to distribution of controlled 15 substances?</p> <p>16 A. No.</p> <p>17 Q. Are you familiar with the 18 claims asserted in this litigation?</p> <p>19 A. In a general sense only.</p> <p>20 Q. And generally speaking, what do 21 you understand the claims to be?</p> <p>22 A. I understand that there are 23 several -- there's a multiparty group 24 asserting that a large number of defendants 25 are responsible for opioids.</p>

Page 22	Page 24
<p>1 Q. Anything else?</p> <p>2 A. No.</p> <p>3 Q. Okay. Do you have a view as to</p> <p>4 the merits of any of the claims?</p> <p>5 A. No.</p> <p>6 Q. And when did you learn about</p> <p>7 this litigation?</p> <p>8 A. I think I heard a little bit</p> <p>9 about it on 60 Minutes, and then -- then</p> <p>10 certainly as I was contacted relevant to this</p> <p>11 case.</p> <p>12 Q. Do you recall when you saw that</p> <p>13 60 Minutes episode?</p> <p>14 A. No. And to be clear, I did not</p> <p>15 see the 60 Minutes episode. I just saw the</p> <p>16 advertisement for the 60 Minutes episode. I</p> <p>17 never watched it.</p> <p>18 Q. Thanks for clarifying.</p> <p>19 Any idea as far as how many</p> <p>20 years ago that was or how recently you saw</p> <p>21 the advertisement?</p> <p>22 A. I -- no.</p> <p>23 Q. Okay. And thank you for</p> <p>24 running through your positions at</p> <p>25 Mallinckrodt earlier.</p>	<p>1 to 2009, you were given no training at</p> <p>2 Mallinckrodt with regard to the Controlled</p> <p>3 Substances Act?</p> <p>4 A. Yes.</p> <p>5 Q. And can you describe the</p> <p>6 training that you were given?</p> <p>7 A. Yes. Our members of our</p> <p>8 compliance team, DEA compliance team, talked</p> <p>9 about the importance of compliance, my</p> <p>10 obligations, as in my role, and the</p> <p>11 obligations of my team members.</p> <p>12 Q. And what did you understand</p> <p>13 those obligations to be?</p> <p>14 A. Well, the first was to process</p> <p>15 orders carefully and diligently, paying</p> <p>16 attention to 222 forms and making sure those</p> <p>17 were accurate.</p> <p>18 And the second was to ensure</p> <p>19 that from the moment we accepted an order to</p> <p>20 the moment it was delivered that it was</p> <p>21 secure, it was done properly and securely,</p> <p>22 and that if any anomaly or anything took</p> <p>23 place, like I said, a delivery exception, it</p> <p>24 was our responsibility to report that</p> <p>25 immediately.</p>
<p style="text-align: center;">Page 23</p> <p>1 For each position, did your</p> <p>2 duties require you to be familiar with the</p> <p>3 Controlled Substances Act or regulations</p> <p>4 thereunder?</p> <p>5 A. No.</p> <p>6 MR. BERG: Object to form.</p> <p>7 A. No.</p> <p>8 QUESTIONS BY MS. KEECH:</p> <p>9 Q. In any of your positions at</p> <p>10 Mallinckrodt, were you given any training</p> <p>11 regarding the Controlled Substances Act or</p> <p>12 any of its regulations?</p> <p>13 A. Yes.</p> <p>14 Q. And can you please describe</p> <p>15 which positions required you -- or provided</p> <p>16 that training?</p> <p>17 A. As director of customer service</p> <p>18 for pharmaceuticals.</p> <p>19 Q. Any other positions?</p> <p>20 A. No.</p> <p>21 Q. And what year did you become</p> <p>22 director?</p> <p>23 A. In 2009.</p> <p>24 Q. 2009.</p> <p>25 So is it fair to say that prior</p>	<p style="text-align: center;">Page 25</p> <p>1 Q. So you had a responsibility to</p> <p>2 report anomalies. Can you give an example of</p> <p>3 the type of anomaly?</p> <p>4 A. Yes. If a recipient of our</p> <p>5 product called and said, hey, I'm short a</p> <p>6 bottle of pills, we would immediately report</p> <p>7 that to the DEA.</p> <p>8 I'm sorry. We really -- I</p> <p>9 wouldn't report it to the DEA. I would</p> <p>10 report it to our DEA compliance team, and I</p> <p>11 believe they would report it to the DEA.</p> <p>12 Q. When you would raise issues</p> <p>13 with the DEA compliance team internally at</p> <p>14 Mallinckrodt, would you then receive</p> <p>15 verification that that issue was actually</p> <p>16 reported to the DEA?</p> <p>17 A. I don't recall.</p> <p>18 Q. So fair to say you trusted that</p> <p>19 the DEA compliance team would follow through</p> <p>20 with whatever you raised to them?</p> <p>21 MR. BERG: Object to form.</p> <p>22 A. Yes.</p> <p>23 QUESTIONS BY MS. KEECH:</p> <p>24 Q. And can you describe your job</p> <p>25 description as a customer service</p>

Page 26	Page 28
<p>1 representative and director?</p> <p>2 A. Which particular -- I had</p> <p>3 several roles. Each was a different job.</p> <p>4 Q. Actually, if you could walk</p> <p>5 through each of them, that would be great.</p> <p>6 A. Sure. As a customer service</p> <p>7 representative in the respiratory division of</p> <p>8 Mallinckrodt, I assisted distributors and</p> <p>9 hospitals, home healthcare providers, with</p> <p>10 tracheostomy and tracheotomy tubes,</p> <p>11 temperature monitoring devices and pulse</p> <p>12 oximetry. So mainly it was order entry,</p> <p>13 letting people know where their orders were,</p> <p>14 and then very low-level troubleshooting,</p> <p>15 helping them with returns.</p> <p>16 Q. And your role as customer</p> <p>17 service director?</p> <p>18 A. In which -- I was a customer</p> <p>19 service director in several groups.</p> <p>20 Q. In each of your capacities.</p> <p>21 A. So as customer service director</p> <p>22 for respiratory and monitoring solutions and</p> <p>23 imaging solutions, I had a few different</p> <p>24 groups. On the respiratory side, we were</p> <p>25 mostly selling medical devices -- no,</p>	<p>1 respiratory group out of my -- mine and</p> <p>2 transferring them over to another location,</p> <p>3 so I worked on that.</p> <p>4 And then I also assumed</p> <p>5 responsibility for our active pharmaceutical</p> <p>6 ingredients group and our dosage group.</p> <p>7 Q. So when you assumed</p> <p>8 responsibility for active pharmaceutical</p> <p>9 ingredients or API and dosage, can you</p> <p>10 describe your responsibilities in that role</p> <p>11 or that capacity?</p> <p>12 A. Sure. The API customer service</p> <p>13 team accepted orders from manufacturers and a</p> <p>14 lot of that product is made to order, and so</p> <p>15 then coordinated with our manufacturing team,</p> <p>16 our planning team, on the timing and delivery</p> <p>17 of that.</p> <p>18 And then the dosage group</p> <p>19 sold -- primarily sold, you know, dosage</p> <p>20 pharmaceuticals to wholesalers, and that team</p> <p>21 accepted orders, advised on order status and,</p> <p>22 you know, assisted with returns, if any.</p> <p>23 Q. So in your role as director of</p> <p>24 global customer service, who did you report</p> <p>25 to?</p>
<p style="text-align: center;">Page 27</p> <p>1 exclusively selling medical devices, so</p> <p>2 pulse oximetry, tracheostomy, tracheotomy</p> <p>3 tubes. I'm sure I'm missing some too, but a</p> <p>4 lot of devices, a lot of those are</p> <p>5 disposable.</p> <p>6 Then in the imaging side, we</p> <p>7 had two unique businesses. One is contrast</p> <p>8 media, so dyes used for X-ray, right, and so</p> <p>9 I was assist -- so there our customers were</p> <p>10 hospitals and imaging centers and</p> <p>11 distributors.</p> <p>12 And then on the nuclear -- then</p> <p>13 we also had a nuclear medicine division, so</p> <p>14 there we are making nuclear medicine,</p> <p>15 radioactive, for procedures. We're</p> <p>16 chartering planes and flying that medicine to</p> <p>17 hospitals and then getting couriers to drive</p> <p>18 it to the hospital so that it can be given to</p> <p>19 the patient while it's still actively</p> <p>20 radioactive. And that was my respiratory and</p> <p>21 imaging job.</p> <p>22 Then in '99, as director of</p> <p>23 pharma and respiratory and imaging, I also --</p> <p>24 so I retained those three groups and then</p> <p>25 worked on the planned separation of the</p>	<p style="text-align: center;">Page 29</p> <p>1 A. So in my role as -- I reported</p> <p>2 to -- in my role as director of global</p> <p>3 customer service, I reported to the director</p> <p>4 of global supply chain.</p> <p>5 Q. And who was that?</p> <p>6 A. George Morrison.</p> <p>7 Q. And was he -- were you his</p> <p>8 direct report when you left Mallinckrodt?</p> <p>9 A. Yes.</p> <p>10 No, I'm sorry. Right before I</p> <p>11 left Mallinckrodt, we restructured, and I was</p> <p>12 no longer his direct report at that time.</p> <p>13 Q. And who was your supervisor at</p> <p>14 that point in time?</p> <p>15 A. Kassie Harrold.</p> <p>16 Q. And did she evaluate your</p> <p>17 performance?</p> <p>18 A. No.</p> <p>19 Q. Did George Morrison?</p> <p>20 A. Yes.</p> <p>21 Q. And how was the evaluation</p> <p>22 conducted? How frequently?</p> <p>23 A. Annually.</p> <p>24 Q. Is there a written record of</p> <p>25 your annual review?</p>

Page 30	Page 32
<p>1 A. Yes. I would -- well, I would 2 assume so, but I don't have any knowledge if 3 it was -- you know, of where it is or whether 4 it was retained.</p> <p>5 Q. Okay. So you don't know who 6 would maintain those performance evaluations?</p> <p>7 A. No.</p> <p>8 Q. And when you were evaluated, 9 were you evaluated based on any particular 10 metrics?</p> <p>11 A. Yes.</p> <p>12 Q. Do you recall what they were?</p> <p>13 A. Yes. Call answer rate, so the 14 percentage of calls answered within 30 15 seconds; order accuracy, as an expression of 16 Sigma.</p> <p>17 Q. Any other factors?</p> <p>18 A. None that I can remember.</p> <p>19 Q. Do you recall if your 20 performance was at all tied to sales?</p> <p>21 A. Yes, I do recall. No, it was 22 not.</p> <p>23 Q. And you indicated that you left 24 Mallinckrodt in March of 2017. Is that 25 correct?</p>	<p>1 A. I don't believe so. 2 Q. Were there any other 3 restrictions in the severance agreement? 4 A. I don't recall the specifics of 5 the severance agreement.</p> <p>6 Q. Do you still have it?</p> <p>7 A. I do.</p> <p>8 Q. Did you disclose it?</p> <p>9 A. Yes.</p> <p>10 MS. KEECH: And, Counsel, I 11 would ask that if that document hasn't 12 already been disclosed that you please 13 do so.</p> <p>14 MR. BERG: Understood. We'll 15 look into it.</p> <p>16 QUESTIONS BY MS. KEECH:</p> <p>17 Q. So up until you left 18 Mallinckrodt, did you consider yourself a 19 successful director of global customer 20 service?</p> <p>21 A. I never really thought about 22 it.</p> <p>23 Q. Did you ever think about your 24 performance as a Mallinckrodt employee?</p> <p>25 A. Yes.</p>
<p style="text-align: center;">Page 31</p> <p>1 A. Yes.</p> <p>2 Q. And what were the circumstances 3 under which you left?</p> <p>4 A. We had done a lot of 5 restructuring, and so I left as part of that.</p> <p>6 Q. Was it voluntary?</p> <p>7 A. I don't know. I had asked -- I 8 had said I would be interested in leaving and 9 making a career change. At the same time, I 10 don't know -- you know, you don't really get 11 to choose that, right, so I don't know how to 12 answer that.</p> <p>13 Q. When you left Mallinckrodt, did 14 you receive a severance payment?</p> <p>15 A. Yes.</p> <p>16 Q. And what was the amount of the 17 severance?</p> <p>18 A. It was -- I was there for 17 19 years, and I received [REDACTED] for 20 every year. So [REDACTED] of salary.</p> <p>21 Q. Did you have a severance 22 agreement?</p> <p>23 A. Yes.</p> <p>24 Q. And did it limit what you were 25 allowed to say about Mallinckrodt?</p>	<p style="text-align: center;">Page 33</p> <p>1 Q. And what did you think about 2 your performance?</p> <p>3 A. I think I was a good employee.</p> <p>4 Q. You complied with workplace 5 rules?</p> <p>6 A. Yes.</p> <p>7 Q. And you did your job the way 8 that Mallinckrodt expected you to do your 9 job?</p> <p>10 A. Yes.</p> <p>11 Q. Would you say that you were 12 well regarded by your peers at Mallinckrodt?</p> <p>13 A. I'd say it was mixed, like any 14 other place.</p> <p>15 Q. What about your supervisors? 16 Do you have an impression of what their view 17 of you was?</p> <p>18 A. Yes.</p> <p>19 Q. And what was that?</p> <p>20 A. Based on my performance 21 evaluations, my supervisors considered me 22 anywhere from a good employee to a 23 superlative employee.</p> <p>24 Q. And would you say that you're 25 detail-oriented?</p>

<p style="text-align: right;">Page 34</p> <p>1 A. No.</p> <p>2 Q. So not detail-oriented, but</p> <p>3 order accuracy was one of your performance</p> <p>4 metrics?</p> <p>5 MR. BERG: Object to form.</p> <p>6 A. The order accuracy of my team</p> <p>7 was one of our performance metrics.</p> <p>8 QUESTIONS BY MS. KEECH:</p> <p>9 Q. Were you personally evaluated</p> <p>10 with regard to order accuracy?</p> <p>11 A. I did not enter orders after --</p> <p>12 you know, after I became supervisor of</p> <p>13 customer service.</p> <p>14 Q. Okay. So as global customer</p> <p>15 service director, how -- strike that.</p> <p>16 In your capacity as global</p> <p>17 customer service director, did you get to</p> <p>18 know your customers?</p> <p>19 A. Not very many.</p> <p>20 Q. Were there some that you were</p> <p>21 more well acquainted with than others?</p> <p>22 A. Yes.</p> <p>23 Q. And do you recall which</p> <p>24 customers?</p> <p>25 A. Yes. I'd refer to them as the</p>	<p style="text-align: right;">Page 36</p> <p>1 organizations.</p> <p>2 Q. How would you define "large</p> <p>3 group"? More or less than five?</p> <p>4 A. More than five.</p> <p>5 Q. And did you get to know the Big</p> <p>6 Three customers?</p> <p>7 A. No. I mean, not well or...</p> <p>8 Q. What did you know about their</p> <p>9 companies?</p> <p>10 A. Going through each, one is</p> <p>11 efficiency. We are very interested in</p> <p>12 efficiency and doing things right, and we</p> <p>13 shared that mutual interest. I think that</p> <p>14 was universal.</p> <p>15 Other than that, I don't really</p> <p>16 recall anything specific about any of these</p> <p>17 companies or really the individuals in them.</p> <p>18 Q. No specific recollections about</p> <p>19 any of the Big Three companies?</p> <p>20 A. No.</p> <p>21 Q. Did you seek to retain</p> <p>22 customers?</p> <p>23 A. No.</p> <p>24 Q. So no effort was put into</p> <p>25 retaining customers as the director of</p>
<p style="text-align: right;">Page 35</p> <p>1 Big Three; McKesson, Cardinal, and ABC. Then</p> <p>2 also the nuclear medicine customers, the</p> <p>3 pharmacists. That's such a unique business</p> <p>4 and a very small community; one learns them</p> <p>5 fairly... and then definitely</p> <p>6 internationally, my international customers,</p> <p>7 but it's more as affiliates, right, so the</p> <p>8 international affiliates, I got to know them.</p> <p>9 Q. Can you describe your</p> <p>10 relationship with each of the Big Three?</p> <p>11 A. Professional.</p> <p>12 Q. Both professionally and</p> <p>13 personally if --</p> <p>14 A. No, that was my description.</p> <p>15 It was a professional relationship.</p> <p>16 Q. Did you ever attend dinners</p> <p>17 with any individuals from the Big Three?</p> <p>18 A. As part of a group, probably</p> <p>19 over the course of several years, maybe five</p> <p>20 to seven.</p> <p>21 Q. And do you recall who else was</p> <p>22 present at those dinners?</p> <p>23 A. Not specifically, no. But it</p> <p>24 usually involved -- it always involved a</p> <p>25 larger group of people from both</p>	<p style="text-align: right;">Page 37</p> <p>1 customer --</p> <p>2 A. Correct. We had no initiative</p> <p>3 based on customer retention.</p> <p>4 Q. And which customers were you</p> <p>5 responsible for?</p> <p>6 A. In which role?</p> <p>7 Q. In your last role at</p> <p>8 Mallinckrodt.</p> <p>9 A. In my last role at</p> <p>10 Mallinckrodt, I was responsible for our</p> <p>11 nuclear medicine pharmacies, our</p> <p>12 international affiliates, our -- quite</p> <p>13 simply, anyone who placed an order with</p> <p>14 Mallinckrodt. That's probably a better</p> <p>15 answer.</p> <p>16 Q. Do you recall what your salary</p> <p>17 was when you started at Mallinckrodt?</p> <p>18 A. No, not specifically. It was</p> <p>19 under [REDACTED] a year, I remember that.</p> <p>20 Q. Did you receive raises while</p> <p>21 you were there?</p> <p>22 A. Yes.</p> <p>23 Q. And can you walk me through</p> <p>24 your raises that you received and when you</p> <p>25 received them, to the extent that you</p>

<p style="text-align: right;">Page 38</p> <p>1 remember?</p> <p>2 A. I can't remember my raises. I 3 don't remember any of the circumstances 4 around my raises.</p> <p>5 Q. Do you recall what your salary 6 was when you left Mallinckrodt?</p> <p>7 A. Yes.</p> <p>8 Q. And what was it?</p> <p>9 A. About [REDACTED].</p> <p>10 Q. Did you also receive bonuses 11 while you were there?</p> <p>12 A. Yes.</p> <p>13 Q. And do you recall the size of 14 the bonus when you left?</p> <p>15 A. No. I'd need to know 16 specifically what bonus you are talking 17 about.</p> <p>18 Q. Did you receive multiple 19 bonuses?</p> <p>20 A. Yes.</p> <p>21 Q. Can you describe to me the 22 various bonuses you received?</p> <p>23 A. Yes. I received usually a 24 yearly bonus. Also, there was one time, and 25 I'm unsure of the year, I received a</p>	<p style="text-align: right;">Page 40</p> <p>1 spin of Mallinckrodt from Covidien. A few 2 other directors in the supply chain had 3 already left. The supply chain lead was 4 leaving and so they -- and so I was, you 5 know, asked to -- I was offered this.</p> <p>6 Q. And prior to receiving this 7 retention bonus, did you express 8 dissatisfaction to anyone at Mallinckrodt 9 regarding your employment there?</p> <p>10 A. I don't recall.</p> <p>11 Q. In the second paragraph on this 12 document, it says: Because your knowledge 13 and skills are critical to the company during 14 this transition period, you are eligible for 15 a payment of [REDACTED].</p> <p>16 What knowledge and skills did 17 you have that you believe were critical to 18 Mallinckrodt?</p> <p>19 MR. BERG: Object to form.</p> <p>20 A. I don't know. I mean, I didn't 21 ask for this payment and I was a bit -- I was 22 very pleased to get it.</p> <p>23 QUESTIONS BY MS. KEECH:</p> <p>24 Q. Okay. Thank you.</p> <p>25 So going back to the customers,</p>
<p style="text-align: right;">Page 39</p> <p>1 retention bonus. And then -- and usually the 2 bonuses were by year, but sometimes for 3 restructuring purposes and everything, that 4 bonus got paid out because we changed a 5 fiscal year or something, it got paid out, 6 like it wasn't a full year.</p> <p>7 And then when I left, I 8 think -- I'd have to check, but I think I may 9 have gotten a partial prorated kind of bonus 10 at my departure, or maybe really prior to my 11 departure but around the same time.</p> <p>12 Q. I'm handing you what's been 13 marked as Exhibit 2, bearing Bates stamp 14 MNK-T1_0007219867.</p> <p>15 (Mallinckrodt-Saffold Exhibit 2 16 was marked for identification.)</p> <p>17 QUESTIONS BY MS. KEECH:</p> <p>18 Q. Do you recognize that document?</p> <p>19 A. Yes.</p> <p>20 Q. And is that the retention bonus 21 that you just referred to?</p> <p>22 A. It is.</p> <p>23 Q. What were the circumstances 24 surrounding this retention payment?</p> <p>25 A. We were trying to execute a</p>	<p style="text-align: right;">Page 41</p> <p>1 how much information was available to you 2 about Mallinckrodt's customers?</p> <p>3 A. Some. And it would depend on 4 the role, so I guess in which role are you 5 referring to?</p> <p>6 Q. As the director of global 7 customer service.</p> <p>8 A. So I saw -- what would be 9 available to me would be pretty much to whom 10 we shipped and to whom we've sent invoices.</p> <p>11 Q. Can you describe your level of 12 interaction with the Big Three customers?</p> <p>13 A. Limited. Professional.</p> <p>14 Q. Did you have a role in 15 generating opioid sales?</p> <p>16 A. No.</p> <p>17 Q. Did anyone under customer 18 service review peculiar or unusual orders?</p> <p>19 A. Yes.</p> <p>20 Q. And who did that?</p> <p>21 MR. BERG: Object to form.</p> <p>22 A. Certainly the manager of -- it 23 would depend on the time period. But 24 generally, in my role as director of global 25 pharmaceuticals, the manager of dosage</p>

Page 42	Page 44	
<p>1 customer service and -- did.</p> <p>2 QUESTIONS BY MS. KEECH:</p> <p>3 Q. And during what time period did</p> <p>4 the manager of dosage review peculiar orders?</p> <p>5 A. I'm not 100% sure I could tell</p> <p>6 you.</p> <p>7 Q. Prior to 2009?</p> <p>8 A. I couldn't tell you anything</p> <p>9 about that prior to 2009.</p> <p>10 Q. Did customer service</p> <p>11 representatives ever monitor peculiar or</p> <p>12 suspicious orders?</p> <p>13 A. No.</p> <p>14 Q. Are you aware that Mallinckrodt</p> <p>15 had a duty to design and implement a</p> <p>16 Suspicious Order Monitoring program?</p> <p>17 MR. BERG: Object to form.</p> <p>18 A. Yes.</p>	<p>1 that Mallinckrodt audited?</p> <p>2 A. No.</p> <p>3 Q. So you just indicated you don't</p> <p>4 know the purpose of an audit. Do you know</p> <p>5 the mechanics of an audit, in general terms?</p> <p>6 A. I know the mechanics of an</p> <p>7 audit when I undergo an audit. I do not know</p> <p>8 the mechanics of a customer audit.</p> <p>9 Q. So you don't know what</p> <p>10 Mallinckrodt would look at?</p> <p>11 A. No.</p> <p>12 Q. Who it spoke with?</p> <p>13 A. Huh-uh.</p> <p>14 Q. Okay. You're not aware of</p> <p>15 whether Mallinckrodt had a specific audit</p> <p>16 procedure to follow?</p> <p>17 A. No, I'm not aware of any audit</p> <p>18 procedures, other than our own -- other than</p> <p>19 what were Mallinckrodt's own internal audit</p> <p>20 so -- but I'm not aware of any other audit.</p> <p>21 Q. When you describe</p> <p>22 Mallinckrodt's own internal audit, what are</p> <p>23 you referring to?</p> <p>24 A. Our people from our internal</p> <p>25 audit company. Our audit group, not company,</p>	
<p>26 QUESTIONS BY MS. KEECH:</p> <p>27 Q. And were you aware of that duty</p> <p>28 when you were employed by Mallinckrodt?</p> <p>29 MR. BERG: Object to form.</p> <p>30 A. Yes.</p> <p>31 QUESTIONS BY MS. KEECH:</p> <p>32 Q. Who informed you of that duty?</p>	<p>33 Page 43</p> <p>34 A. Our global DEA compliance lead.</p> <p>35 Q. And do you recall when you</p> <p>36 learned of this duty?</p> <p>37 A. Not specifically, but during</p> <p>38 the onboarding process from moving from</p> <p>39 respiratory into imaging, so July-ish of</p> <p>40 2009.</p> <p>41 Q. And were you personally</p> <p>42 involved in monitoring suspicious orders</p> <p>43 during your employment at Mallinckrodt?</p> <p>44 A. No.</p> <p>45 Q. Were you involved in auditing</p> <p>46 any of Mallinckrodt's customers?</p> <p>47 A. No.</p> <p>48 Q. Do you know whether</p> <p>49 Mallinckrodt conducted audits of its</p> <p>50 customers?</p> <p>51 A. Yes.</p> <p>52 Q. And what do you understand the</p> <p>53 purpose of an audit to be?</p> <p>54 A. I don't know.</p> <p>55 Q. Do you know how Mallinckrodt</p> <p>56 determined who to audit?</p> <p>57 A. No.</p> <p>58 Q. Do you recall which entities</p>	<p>59 Page 45</p> <p>60 looking at my function, right, to make sure</p> <p>61 we were complying with financial regulations.</p> <p>62 Q. So you are aware of a group</p> <p>63 within Mallinckrodt that was auditing your</p> <p>64 capacity?</p> <p>65 A. Yes.</p> <p>66 Q. But fair to say you're not</p> <p>67 aware of whether Mallinckrodt audited any of</p> <p>68 its customers?</p> <p>69 A. I was aware that Mallinckrodt</p> <p>70 did audit customers, but I have no detailed</p> <p>71 knowledge or actually any knowledge at all</p> <p>72 what that really meant, means.</p> <p>73 Q. Okay. And were you aware that</p> <p>74 in 2010, Mallinckrodt identified various</p> <p>75 indirect customers who were purchasing from</p> <p>76 multiple Mallinckrodt distributors?</p> <p>77 A. No.</p> <p>78 Q. Did you ever make a</p> <p>79 determination that a customer had suspicious</p> <p>80 orders?</p> <p>81 A. No.</p> <p>82 Q. Are you aware of whether</p> <p>83 Mallinckrodt ever made a determination that</p> <p>84 any of its customers had suspicious orders?</p>

Page 46	Page 48
<p>1 A. No.</p> <p>2 Q. Are you aware that</p> <p>3 manufacturers and distributors of narcotics</p> <p>4 must comply with the Controlled Substances</p> <p>5 Act?</p> <p>6 MR. BERG: Object to form.</p> <p>7 A. Yes.</p> <p>8 QUESTIONS BY MS. KEECH:</p> <p>9 Q. Are opioids narcotics?</p> <p>10 MR. BERG: Object to form.</p> <p>11 A. Yes, I think so.</p> <p>12 QUESTIONS BY MS. KEECH:</p> <p>13 Q. And Mallinckrodt manufacturers</p> <p>14 opioids, correct?</p> <p>15 A. Yes.</p> <p>16 Q. And are you familiar with the</p> <p>17 requirements of the Controlled Substances Act</p> <p>18 as it relates to a manufacturer of controlled</p> <p>19 substances?</p> <p>20 A. No. Only as the -- no.</p> <p>21 Just -- I'm not, really.</p> <p>22 Q. So earlier, when you indicated</p> <p>23 that members of DEA compliance talk about the</p> <p>24 importance of compliance, did they ever</p> <p>25 discuss the Controlled Substances Act?</p>	<p>1 whether it was a manual or electronic order.</p> <p>2 Second was to protect the</p> <p>3 integrity of the supply chain. So, you know,</p> <p>4 so there's a certain amount of</p> <p>5 confidentiality that we maintained so that</p> <p>6 way bad guys couldn't find out where product</p> <p>7 was going, right. And that, it was even for</p> <p>8 my systems, so I then made sure that people</p> <p>9 who hadn't passed a DEA background check</p> <p>10 didn't have access to this information.</p> <p>11 And then the third was to</p> <p>12 report any -- any discrepancy. So if it was,</p> <p>13 you know, a misdelivery, mis-shipment,</p> <p>14 somebody tampered with a package, right, I'd</p> <p>15 make sure that my team was reporting that to</p> <p>16 our DEA team and recording that. So that was</p> <p>17 very important.</p> <p>18 And then really, anything --</p> <p>19 you know, and then to collaborate, you know,</p> <p>20 with other members of Mallinckrodt kind of at</p> <p>21 the direction of the DEA compliance team to</p> <p>22 make sure we're -- any other area where we</p> <p>23 can demonstrate compliance.</p> <p>24 Q. Are you familiar with the term</p> <p>25 "closed system" for opioid distribution?</p>
<p>1 A. In general terms, yes. Like,</p> <p>2 hey, you have to comply, and it's very</p> <p>3 important to do so. And here's what we think</p> <p>4 you need to do to comply, and take that</p> <p>5 seriously. And that's kind of the context</p> <p>6 and the thrust of the message.</p> <p>7 Q. Do you feel that your training</p> <p>8 was adequate with regard to what your duties</p> <p>9 and responsibilities were?</p> <p>10 A. Yes.</p> <p>11 Q. But you don't recall what any</p> <p>12 of those duties and responsibilities are?</p> <p>13 MR. BERG: Object to form.</p> <p>14 A. I understand my duties and</p> <p>15 responsibilities and how they relate to</p> <p>16 compliance.</p> <p>17 QUESTIONS BY MS. KEECH:</p> <p>18 Q. Can you describe your duties</p> <p>19 and responsibilities as they relate to</p> <p>20 compliance?</p> <p>21 A. Yes. Our first responsibility</p> <p>22 was to make sure that the order placed was a</p> <p>23 valid order, so we checked against -- well,</p> <p>24 first of all, we maintained systems and</p> <p>25 processes that could validate the order,</p>	<p>1 A. No.</p> <p>2 Q. This means that only people or</p> <p>3 entities that are registrants under the</p> <p>4 Controlled Substances Act can be involved in</p> <p>5 the distribution of controlled substances.</p> <p>6 MR. BERG: Object to form.</p> <p>7 QUESTIONS BY MS. KEECH:</p> <p>8 Q. Does that sound familiar?</p> <p>9 MR. BERG: Object to form.</p> <p>10 A. The term and your statement</p> <p>11 don't sound familiar, but the concept, yes,</p> <p>12 that's -- that was very important.</p> <p>13 QUESTIONS BY MS. KEECH:</p> <p>14 Q. And that concept, would you</p> <p>15 agree that the purpose of that is to minimize</p> <p>16 theft and diversion of controlled substances?</p> <p>17 A. Yes.</p> <p>18 Q. And would you agree that a</p> <p>19 registrant's failure to meet its obligations</p> <p>20 under the Controlled Substances Act can</p> <p>21 result in controlled substances being</p> <p>22 diverted from legitimate channels?</p> <p>23 A. I don't know. I'm not really a</p> <p>24 controlled -- you know, I'm not an expert on</p> <p>25 the Controlled Substances Act or diversion,</p>
Page 47	Page 49

Page 50	Page 52
<p>1 so it's tough for me to speculate kind of 2 downstream. I just understood my obligation, 3 right, was to...</p> <p>4 Q. Would you agree that a 5 manufacturer that sells controlled substances 6 to distribute -- to distributors who then 7 recklessly distribute opioids is engaged in 8 diversion?</p> <p>9 MR. BERG: Object to form.</p> <p>10 A. I'm not really an expert on 11 even what diversion is, right. So my view of 12 diversion is like you get it from point A to 13 point B and make sure that it's where -- 14 it's going where it's supposed to and that 15 it's approved and compliant.</p> <p>16 QUESTIONS BY MS. KEECH:</p> <p>17 Q. So what do effective controls 18 to prevent diversion mean to you?</p> <p>19 MR. BERG: Object to form.</p> <p>20 A. Well, I certainly can't speak 21 to all aspects of diversion. I'm not sure 22 there's even a universal definition. So I'm 23 not sure I can answer the question, really.</p> <p>24 QUESTIONS BY MS. KEECH:</p> <p>25 Q. The Controlled Substances Act</p>	<p>1 but I'm not, you know -- I'm not an expert on 2 that.</p> <p>3 QUESTIONS BY MS. KEECH:</p> <p>4 Q. Do you know if they had a duty 5 to report suspicious orders to the DEA?</p> <p>6 MR. BERG: Object to form.</p> <p>7 A. Yes. I understood that they 8 did have a duty to report suspicious orders 9 to the DEA.</p> <p>10 QUESTIONS BY MS. KEECH:</p> <p>11 Q. And Mallinckrodt's distributor 12 customers are called direct customers, 13 correct?</p> <p>14 A. I don't -- I don't think that's 15 a statement you can make universally. We had 16 a lot of lines of business, and so people 17 used those terms really poorly.</p> <p>18 So, no, people may have called 19 them that, but they may not have as well.</p> <p>20 Q. How did you refer to 21 Mallinckrodt's distributor customers?</p> <p>22 A. As distributors and 23 wholesalers.</p> <p>24 Q. Okay. How about customers that 25 those distributors and wholesalers then sold</p>
<p>1 requires a Suspicious Order Monitoring 2 system, correct?</p> <p>3 MR. BERG: Object to form.</p> <p>4 A. I don't know.</p> <p>5 QUESTIONS BY MS. KEECH:</p> <p>6 Q. What does the term "Suspicious 7 Order Monitoring system" mean to you?</p> <p>8 MR. BERG: Object to form.</p> <p>9 A. So in the context of my role, 10 my understanding is it's required by the DEA 11 to -- that Mallinckrodt as an entity is 12 required to have a Suspicious Order 13 Monitoring program and that my team 14 interacted with our DEA compliance team to 15 kind of ensure compliance with that.</p> <p>16 QUESTIONS BY MS. KEECH:</p> <p>17 Q. And Mallinckrodt had a 18 Suspicious Order Monitoring program, correct?</p> <p>19 A. Yes.</p> <p>20 Q. Did Mallinckrodt have a duty to 21 identify suspicious orders of Mallinckrodt 22 products?</p> <p>23 MR. BERG: Object to form.</p> <p>24 A. I think that was a requirement 25 of the Suspicious Order Monitoring program,</p>	<p>1 product to?</p> <p>2 MR. BERG: Object to form.</p> <p>3 A. Can you repeat that?</p> <p>4 QUESTIONS BY MS. KEECH:</p> <p>5 Q. Sure.</p> <p>6 Did you have a term for the 7 customers of Mallinckrodt's distributor 8 customers?</p> <p>9 A. Yes. Like distributors and 10 wholesalers. Oh, for their customers?</p> <p>11 Q. Correct.</p> <p>12 A. Okay, I'm sorry. Not one that 13 would apply to them universally, right. So 14 if a distributor sold it to a pharmacy, we 15 would say -- you know, I would call them a 16 pharmacy. Or if they sold them to a clinic, 17 a clinic or to a PBM, I'd say a PBM.</p> <p>18 So I'm not sure there was a -- 19 I'm not familiar with like a nomenclature for 20 that group of people you're referring to.</p> <p>21 Q. Did you ever hear either the 22 term "indirect" or "downstream" customer for 23 those entities?</p> <p>24 A. I don't recall that.</p> <p>25 Q. We've been going about an hour.</p>

Page 54	Page 56
<p>1 Would now be a good time for a break? 2 MR. BERG: Sure. 3 MS. KEECH: Okay. Maybe five 4 minutes. Okay. 5 THE VIDEOGRAPHER: Stand by. 6 Off the record at 10:08. 7 (Recess taken, 10:08?a.m. to 8 10:22?a.m.) 9 THE VIDEOGRAPHER: All right, 10 stand by. The time is 10:22. Back on 11 the record.</p> <p>12 QUESTIONS BY MS. KEECH:</p> <p>13 Q. Would you agree that there is 14 an opioid crisis or prescription drug abuse 15 epidemic facing the country?</p> <p>16 MR. BERG: Object to form.</p> <p>17 A. Yes.</p> <p>18 QUESTIONS BY MS. KEECH:</p> <p>19 Q. Have you ever received a 20 communication from Mallinckrodt regarding the 21 existence of an opioid epidemic?</p> <p>22 A. I don't recall.</p> <p>23 Q. In what year did you realize 24 there was an opioid epidemic?</p> <p>25 A. I can't name a specific year.</p>	<p>1 Q. And did you ever come to 2 realize at some point in time that 3 Mallinckrodt's Suspicious Order Monitoring 4 system that Mallinckrodt was using to 5 identify diversion by its distributor clients 6 was not adequate?</p> <p>7 A. No.</p> <p>8 MR. BERG: Object to form.</p> <p>9 A. I'm sorry, I'm not sure you 10 heard me. No.</p> <p>11 QUESTIONS BY MS. KEECH:</p> <p>12 Q. Thank you.</p> <p>13 Do you agree that as a director 14 of customer service, it was important for you 15 to keep up to date on the news about opioid 16 abuse and diversion?</p> <p>17 A. No.</p> <p>18 Q. Did you think it was important 19 for you to know whether any of Mallinckrodt's 20 customers were sanctioned for their business 21 practices related to distribution of 22 Mallinckrodt's products?</p> <p>23 A. For me to know?</p> <p>24 Q. Yes.</p> <p>25 A. No.</p>
<p>1 I think it was -- I'd maybe call it like more 2 of like a gradual understanding.</p> <p>3 Q. And when did you develop this 4 understanding?</p> <p>5 MR. BERG: Object to form.</p> <p>6 A. I'm not sure I know exactly 7 when.</p> <p>8 QUESTIONS BY MS. KEECH:</p> <p>9 Q. Was it while you were still 10 employed by Mallinckrodt or after leaving?</p> <p>11 A. While I was employed.</p> <p>12 Q. Did you ever discuss it with 13 anyone at Mallinckrodt?</p> <p>14 A. No.</p> <p>15 Q. And are you aware of whether 16 Mallinckrodt products have contributed to 17 this problem?</p> <p>18 A. No.</p> <p>19 Q. Mallinckrodt sold oxy 20 15 milligrams and oxy 30 milligrams, correct?</p> <p>21 A. Yes.</p> <p>22 Q. And Mallinckrodt's distributor 23 customers purchased millions of these 24 products from Mallinckrodt, correct?</p> <p>25 A. Yes.</p>	<p>1 Q. And are you familiar with the 2 term "migration" as it applies to opioid 3 products?</p> <p>4 A. No.</p> <p>5 Q. Have you ever heard the phrase 6 "Oxy Express" or "Blue Highway"?</p> <p>7 A. I've heard the phrase "Oxy 8 Express."</p> <p>9 Q. And what do you believe that 10 term or phrase to signify?</p> <p>11 A. Working off of recall, I think 12 it means from like -- I think like up from 13 Florida, up -- kind of up into the northeast 14 corridor, there's like a highway or 15 something.</p> <p>16 Q. And were you aware while you 17 were at Mallinckrodt that a significant 18 number or volume of opioids, particularly 19 oxycodone, was first being sent to Florida 20 where they would then migrate to other 21 states?</p> <p>22 MR. BERG: Object to form.</p> <p>23 A. No.</p> <p>24 QUESTIONS BY MS. KEECH:</p> <p>25 Q. Were you aware that large</p>

<p style="text-align: right;">Page 58</p> <p>1 volumes of Mallinckrodt product were going to 2 Florida? 3 A. No. 4 Q. Ever hear anyone discuss 5 Florida as it relates to an opioid epidemic 6 or problem distributors? 7 A. I've never heard, really, as it 8 relates to opioid epidemic. Yes, as it 9 relates to problem distributors. 10 Q. And what was the context of 11 those communications? 12 A. I can -- you know, to the best 13 that I can recall, it was that there are some 14 distributors who are -- who have been 15 suspended for not following best practice or 16 being out of compliance, and some of their 17 locations were in Florida or maybe they were 18 shipping to Florida, so... 19 (Mallinckrodt-Saffold Exhibit 3 20 was marked for identification.) 21 QUESTIONS BY MS. KEECH: 22 Q. I'm handing you what's been 23 marked as Exhibit 3, bearing Bates numbers 24 MNK-T1_000290150. And this is an e-mail sent 25 from Victor Borelli on Wednesday, July 29th,</p>	<p style="text-align: right;">Page 60</p> <p>1 Q. Do you agree that the illegal 2 distribution of controlled substances 3 currently has a substantial and detrimental 4 effect on the health and general welfare of 5 the American people? 6 MR. BERG: Object to form. 7 A. I'm sorry, can you repeat that 8 question? 9 QUESTIONS BY MS. KEECH: 10 Q. Do you agree that the illegal 11 distribution of controlled substances 12 currently has a substantial and detrimental 13 effect on the health and general welfare of 14 the American people? 15 MR. BERG: Object to form. 16 A. I'm not sure I know enough 17 about the drivers of the prescription drug 18 abuse problems in this country to have 19 formulated an opinion on that. 20 QUESTIONS BY MS. KEECH: 21 Q. Okay. And turning to the first 22 page of this document, it indicates that 23 south Florida has become the largest supplier 24 of illegal prescription drugs in this 25 country.</p>
<p style="text-align: right;">Page 59</p> <p>1 2009. You are on the "to" line. 2 Do you recall receiving this 3 e-mail? 4 A. I don't. 5 Q. Do you have any reason to doubt 6 its authenticity? 7 A. Oh, no. 8 Q. Turning to the second page, can 9 you read aloud the third paragraph down 10 beginning with the phrase "Statistics show"? 11 A. "Statistics show an alarming 12 problem facing America. Prescription drug 13 abuse, which has held steady over the past 14 five years according to the Partnership for a 15 Drug-Free America, with nearly one in five 16 teens abusing prescription medications to get 17 high." 18 Q. And can you read -- 19 A. Oh. "Prescription drug abuse 20 is a significant problem in this country." 21 Q. Thank you. 22 Do you agree with that 23 statement, that prescription drug abuse is a 24 significant problem in this country? 25 A. Yes.</p>	<p style="text-align: right;">Page 61</p> <p>1 Were you aware of that? 2 MR. BERG: Object to form. 3 A. No. Like at the time I -- at 4 what time? 5 QUESTIONS BY MS. KEECH: 6 Q. In 2009. 7 A. So, no, prior to receipt of 8 this; and then, yes, after receipt. 9 Q. So beginning in 2009, after 10 receiving this e-mail, you were aware that 11 south Florida had become the largest supplier 12 of illegal prescriptions in the country? 13 A. Yes. 14 Q. Okay. And were you also aware, 15 as Victor Borelli wrote, that doctor shopping 16 occurs in the state of Florida? 17 A. No firsthand knowledge. 18 Q. Do you have any reason to doubt 19 Victor Borelli's statement there that doctor 20 shopping was happening in Florida? 21 MR. BERG: Object to form. 22 A. No. 23 QUESTIONS BY MS. KEECH: 24 Q. Okay. Are you familiar with 25 the term "pill mill"?</p>

Page 62	Page 64
<p>1 A. Yes.</p> <p>2 Q. And what do you understand that</p> <p>3 to mean?</p> <p>4 A. Well, I think I've seen it used</p> <p>5 in a variety of contexts. Generally it --</p> <p>6 where I've heard the term "pill mill," it has</p> <p>7 referred to a place that does either one of</p> <p>8 two things; writes a lot of prescriptions for</p> <p>9 pain medication, or fills a lot of</p> <p>10 prescriptions for pain medications.</p> <p>11 Q. Thank you.</p> <p>12 (Mallinckrodt-Saffold Exhibit 4</p> <p>13 was marked for identification.)</p> <p>14 QUESTIONS BY MS. KEECH:</p> <p>15 Q. I'm now handing you what's been</p> <p>16 marked as Exhibit 4, a document bearing Bates</p> <p>17 stamp MNK-T1_0007179935.</p> <p>18 (Document review by witness.)</p> <p>19 QUESTIONS BY MS. KEECH:</p> <p>20 Q. This is an e-mail sent from</p> <p>21 Karen Harper to you on October 31st, 2009,</p> <p>22 regarding fentanyl fanny packs.</p> <p>23 Do you recall receiving this</p> <p>24 e-mail?</p> <p>25 A. I don't recall the specifics of</p>	<p>1 mean?</p> <p>2 A. You know, I guess in my</p> <p>3 experience, it -- really, it's what's flagged</p> <p>4 by our compliance and monitoring team as an</p> <p>5 order that we should report and investigate.</p> <p>6 Q. Do you know what</p> <p>7 characteristics Mallinckrodt was looking for</p> <p>8 in order to flag such orders?</p> <p>9 A. Not specifically, but</p> <p>10 characteristics of the anomalous.</p> <p>11 Q. Okay. Did Mallinckrodt</p> <p>12 order -- excuse me. Did Mallinckrodt flag</p> <p>13 orders of unusual size?</p> <p>14 A. I don't recall.</p> <p>15 Q. Did Mallinckrodt flag orders</p> <p>16 deviating substantially from a normal</p> <p>17 pattern?</p> <p>18 A. You know, I'm not familiar with</p> <p>19 how orders were flagged, and I also think the</p> <p>20 program may have changed even during my</p> <p>21 tenure there. So I'm not sure I can answer</p> <p>22 that with any kind of confidence.</p> <p>23 Q. Okay. So fair to say you don't</p> <p>24 know whether orders of unusual frequency were</p> <p>25 flagged either?</p>
<p>1 it.</p> <p>2 Q. The last sentence or</p> <p>3 second-to-last sentence of Ms. Harper's</p> <p>4 e-mail says: Fentanyl pops accidentally</p> <p>5 obtained by children would lead to certain</p> <p>6 overdose and death.</p> <p>7 MR. BERG: Object to form.</p> <p>8 QUESTIONS BY MS. KEECH:</p> <p>9 Q. Are you aware that people have</p> <p>10 died from overdoses of opioids?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. And do you agree with</p> <p>13 Karen's statement that if Mallinckrodt</p> <p>14 products got into the wrong hands, it could</p> <p>15 result in death?</p> <p>16 MR. BERG: Object to form.</p> <p>17 A. Yes, definitely some</p> <p>18 Mallinckrodt products.</p> <p>19 QUESTIONS BY MS. KEECH:</p> <p>20 Q. Thank you. You can set that</p> <p>21 aside.</p> <p>22 Are you familiar with the term</p> <p>23 "suspicious order"?</p> <p>24 A. Yes.</p> <p>25 Q. And what do you believe that to</p>	<p>1 Page 63</p> <p>1 A. Yes, that's fair.</p> <p>2 Q. Okay. Were you ever trained to</p> <p>3 detect suspicious orders for prescription</p> <p>4 medications?</p> <p>5 A. No.</p> <p>6 Q. Are you familiar with the term</p> <p>7 "peculiar order"?</p> <p>8 A. Yes.</p> <p>9 Q. And can you define that,</p> <p>10 please?</p> <p>11 A. Sure. Peculiar orders were</p> <p>12 orders that attributes were outside of what</p> <p>13 maybe we would expect to be receiving from</p> <p>14 the certain -- from a certain customer at a</p> <p>15 certain time, and they required investigation</p> <p>16 and more information to determine whether or</p> <p>17 not we would, you know, accept the order or</p> <p>18 flag it further.</p> <p>19 Q. So what types of scenarios</p> <p>20 would result in a flag or, in other words,</p> <p>21 they're outside of what Mallinckrodt would</p> <p>22 expect?</p> <p>23 A. Well, again, I'm not an expert,</p> <p>24 right, so I just knew that these orders were</p> <p>25 flagged.</p>

Page 66	Page 68
1 Q. Okay.	1 in his role for quite a while, and I felt
2 A. And so I'd say anything maybe	2 like it was time for him to have a challenge.
3 other than -- a condition other than what we	3 And at the same time, I think,
4 would expect to see, but I'm not sure what	4 you know, I kind of like people
5 the details were.	5 cross-functional and doing that stuff.
6 Q. So can you describe what any	6 Q. So was it your perception that
7 red flags would be?	7 managing dosage was more difficult than
8 A. No, I'm not an expert.	8 managing API or bulk?
9 Q. Were you involved in helping	9 A. No.
10 Mallinckrodt identify any suspicious orders?	10 Q. Just a different experience?
11 A. No.	11 A. Exactly.
12 Q. Were you on the Suspicious	12 Q. Okay. Are you familiar with
13 Order Monitoring team?	13 the term "do not ship list"?
14 A. No.	14 A. Yes.
15 Q. And you said earlier	15 Q. And what is that?
16 Mallinckrodt had an SOM team, correct?	16 A. I can't recall, like,
17 A. Yes.	17 specifically like what it was, but I know we
18 Q. Do you recall when it was	18 had a do not ship list which, at the agent
19 formed?	19 level, they would check orders or, I guess,
20 A. No.	20 customers against.
21 Q. So is it your testimony that	21 Q. So what is your understanding
22 you were not involved in the SOM team in any	22 of the purpose of the do not ship list?
23 way?	23 A. Not to -- not to ship to those
24 A. Oh, that's not my testimony.	24 customers.
25 Q. Okay.	25 Q. And how did an entity end up on
Page 67	Page 69
1 A. I was not a member of the team.	1 the do not ship list?
2 Q. Were you involved in the SOM	2 MR. BERG: Object to form.
3 team in any way?	3 A. I'm not sure.
4 A. Yes.	4 QUESTIONS BY MS. KEECH:
5 Q. How so?	5 Q. Okay.
6 A. I had some direct reports who	6 (Mallinckrodt-Saffold Exhibit 5
7 were on the team.	7 was marked for identification.)
8 Q. And who were your direct	8 QUESTIONS BY MS. KEECH:
9 reports that were on the team?	9 Q. I'm handing you what has been
10 A. Jim Rausch, who is manager of	10 marked as Exhibit 5, bearing Bates number
11 API and then later a manager of dosage, and	11 MNK-T1_000263249.
12 Cathy Stewart, who was manager of dosage and	12 (Document review by witness.)
13 then later API.	13 QUESTIONS BY MS. KEECH:
14 Q. So did Jim Rausch and Cathy	14 Q. Do you recognize this e-mail?
15 Stewart essentially switch positions from API	15 A. No.
16 to dosage?	16 Q. It's an e-mail sent from Cathy
17 A. Yes.	17 Stewart on November 17th, 2009, sent to Karen
18 Q. And when did that switch occur?	18 Harper and Jim Rausch, and you were CC'd
19 A. At the time I began my role or	19 along with Bill Ratliff.
20 almost immediately following it, so in 2009.	20 Do you have any reason to doubt
21 Q. Okay. What was the basis for	21 the authenticity of this e-mail?
22 that switch?	22 A. Oh, no.
23 A. We were kind of restructuring	23 Q. Okay. And this e-mail
24 and thinking about where to move talent, and	24 indicates that Mallinckrodt was planning to
25 I had seen that -- I had learned that Jim was	25 have the do not ship list administered by

Page 70	Page 72
<p>1 CDIG. That's the customer data integrity 2 group? Is that correct? 3 A. Yes. 4 Q. And do you know the 5 circumstances as to why Mallinckrodt was 6 transitioning the do not ship list? 7 A. No. It's -- you know, I think 8 Cathy, in this e-mail that I've read, so I 9 can only assume it's stated by Cathy in this 10 e-mail, that those are the reasons why. 11 Q. And Cathy states on the second 12 page of the e-mail: I'd like to eliminate 13 our manual Excel spreadsheet to keep track of 14 these customers. It's a process that lends 15 itself to errors and omissions. 16 Additionally, although good intentioned, I'm 17 concerned that a customer listed on the do 18 not ship list will inadvertently receive 19 product from us. 20 A. Yes. 21 Q. Would you agree with that? 22 MR. BERG: Object to form. 23 A. Certainly I would -- wouldn't 24 dispute it, but I don't really have firsthand 25 knowledge of that, especially in 2009, I</p>	<p>1 QUESTIONS BY MS. KEECH: 2 Q. Were you aware that certain 3 physicians were under investigation at 4 Mallinckrodt or by Mallinckrodt? 5 MR. BERG: Object to form. 6 A. No. 7 QUESTIONS BY MS. KEECH: 8 Q. Do you know what was involved 9 in this reapproval process that Cathy refers 10 to? 11 A. No. 12 Q. Is your understanding, after 13 ready Cathy Stewart's e-mail here, that 14 essentially, if a company was cut off for 15 suspicious orders, provided they passed a 16 subsequent credit check, that Mallinckrodt 17 could then resume providing product to them? 18 MR. BERG: Object to form. 19 A. No, that's not it. 20 QUESTIONS BY MS. KEECH: 21 Q. What is your understanding of 22 the process after a company was cut off for 23 suspicious orders and then wanted to 24 repurchase product from Mallinckrodt? 25 A. I have limited understanding,</p>
<p>1 wouldn't have -- I was very new to the group. 2 But I would respect the opinion 3 of Cathy on this. 4 QUESTIONS BY MS. KEECH: 5 Q. Okay. And were you aware that 6 at the time Mallinckrodt was using a manual 7 do not ship list? 8 A. Yes. 9 Q. Okay. And do you know how 10 often the manual spreadsheet was updated? 11 A. No. 12 Q. Okay. Cathy goes on to say: 13 We can then proceed with credit doing a check 14 on the website for physicians that are under 15 investigation and how to handle customers who 16 may have been denied shipments previously but 17 have taken steps to clean house and are now 18 reapproved to do business with us again, 19 perhaps even under the same company name. 20 MR. BERG: I'm sorry, where are 21 you reading that from? 22 MS. KEECH: First page. 23 MR. BERG: Okay. I see it now. 24 Thanks. 25 MS. KEECH: Yep.</p>	<p>1 but my understanding is that it was our 2 compliance team, along with Bill Ratliff, who 3 is compliance, but security too, and they 4 were the only ones who could make that 5 decision. 6 Q. Okay. 7 (Mallinckrodt-Saffold Exhibit 6 8 was marked for identification.) 9 QUESTIONS BY MS. KEECH: 10 Q. I'm now handing you what has 11 been marked as Exhibit 6 bearing Mallinckrodt 12 Bates number MNK-T1_0000302469. 13 Do you recognize this document? 14 A. Yes. 15 Q. And what is it? 16 A. It's just -- it's an e-mail 17 from me to my direct report asking him to 18 update his goals. 19 Q. And can you read aloud the 20 stated goal? 21 A. "Ensure compliance with 22 regulatory and internal governance 23 requirements by completing assigned SOX 24 testing before the end of March 2010, by 25 establishing and implementing the procedures</p>

Page 74	Page 76
<p>1 required to support Suspicious Order 2 Monitoring, and by completing SOPs on the 3 order management of controlled substances 4 before the end of Q2."</p> <p>5 Q. Thank you. 6 And you indicated that this was 7 a goal that you were trying to add. What 8 were you trying to add this to? 9 MR. BERG: Object to form. 10 A. To -- we have a system, right, 11 where we put goals in there, and I was trying 12 to get it into Jim's goals in that system. 13 QUESTIONS BY MS. KEECH: 14 Q. Okay. And was this a goal that 15 you generated for him? 16 A. It's a goal we agreed upon. 17 Q. Okay. And what is S-O-X or SOX 18 testing? 19 A. Sarbanes-Oxley. 20 Q. Okay. And can you describe 21 that? 22 A. Sure. 23 So Sarbanes-Oxley is financial 24 controls by reg- -- by law. So one of our 25 requirements in our group was to look at --</p>	<p>1 A. It does say this is an 2 automated e-mail. Please do not reply to 3 this e-mail address. So I don't know if it 4 just used that almost -- my name as almost 5 like an alias. So I don't know. 6 Q. This e-mail indicates that Jim 7 Rausch's individual goal was approved. 8 A. Yes. 9 Q. Is that consistent with your 10 recollection? 11 A. Yes. 12 Q. Okay. And was Jim Rausch's 13 compensation tied to his goal? 14 A. Yes. 15 Q. Do you know whether he 16 accomplished his goal? 17 MR. BERG: Object to form. 18 A. I can't recall. 19 QUESTIONS BY MS. KEECH: 20 Q. Can you tell me more about how 21 his compensation was tied to his goal? 22 A. Yes. So each member of my team 23 during this time period would have a handful 24 of goals, and then based on their rating for 25 each goal, that would roll up to an overall</p>
<p style="text-align: center;">Page 75</p> <p>1 was to test to make sure that we had the 2 proper financial controls in place, and 3 that's to what that referred. 4 (Mallinckrodt-Saffold Exhibit 7 5 was marked for identification.) 6 QUESTIONS BY MS. KEECH: 7 Q. I'm now handing you what has 8 been marked as Exhibit 7, bearing Bates 9 number MNK-T1_0000303789. 10 Do you recognize this? 11 A. No. 12 Q. What is this document? 13 MR. BERG: Object to form. 14 A. Well, I don't know. It looks 15 like it was an automatic e-mail that 16 resulted -- that was a result of maybe the 17 goal getting updated, but that's a guess. 18 QUESTIONS BY MS. KEECH: 19 Q. Okay. It does say that you're 20 on -- that you were the sender of this 21 document. 22 MR. BERG: Object to form. 23 QUESTIONS BY MS. KEECH: 24 Q. Is that correct, according to 25 the document?</p>	<p style="text-align: center;">Page 77</p> <p>1 rating. 2 And then the amount of merit 3 increase I would give to -- not really I 4 would give, but amount of merit increase 5 would be kind of based on their performance 6 rating in addition to other factors like 7 where they were in the market and how much 8 they're currently making. 9 Q. Okay. So were you familiar 10 with the Suspicious Order Monitoring program? 11 MR. BERG: Object to form. 12 A. I was -- I would say no. I was 13 familiar with, you know, our support of the 14 Suspicious Order Monitoring program, but not 15 the program itself. 16 QUESTIONS BY MS. KEECH: 17 Q. Okay. But you oversaw Jim 18 Rausch, who was working on that? 19 A. Yes. Jim Rausch was working on 20 the dosage customer service piece of the 21 Suspicious Order Monitoring program, with our 22 compliance group. 23 Q. Thank you. 24 (Mallinckrodt-Saffold Exhibit 8 25 was marked for identification.)</p>

Page 78	Page 80
<p>1 QUESTIONS BY MS. KEECH:</p> <p>2 Q. I'm handing you what has been</p> <p>3 marked as Exhibit 8, bearing Bates number</p> <p>4 MNK-T1_000263201. This is an e-mail from</p> <p>5 Karen Harper to Cathy Stewart sent on</p> <p>6 January 19th, 2001.</p> <p>7 And in this correspondence,</p> <p>8 Karen e-mails Cathy Stewart following up on</p> <p>9 an e-mail indicating that they turn off the</p> <p>10 30-day cumulative increase trigger until</p> <p>11 George resolves and asking if George</p> <p>12 mentioned anything about having gotten</p> <p>13 feedback on how to fix the formula.</p> <p>14 MR. BERG: Object to form.</p> <p>15 QUESTIONS BY MS. KEECH:</p> <p>16 Q. In this e-mail, do you know</p> <p>17 whether they were referring to you?</p> <p>18 MR. BERG: Object to form.</p> <p>19 A. No.</p> <p>20 QUESTIONS BY MS. KEECH:</p> <p>21 Q. Was there any other George that</p> <p>22 worked with you in Mallinckrodt?</p> <p>23 A. That worked with me? I mean,</p> <p>24 yeah, there were other people named George at</p> <p>25 Mallinckrodt.</p>	<p>1 authenticity?</p> <p>2 A. No.</p> <p>3 Q. This is a Suspicious Order</p> <p>4 Monitoring team charter indicating that the</p> <p>5 team started on March 28, 2008. Is that</p> <p>6 correct?</p> <p>7 MR. BERG: Object to form.</p> <p>8 A. Yes.</p> <p>9 QUESTIONS BY MS. KEECH:</p> <p>10 Q. Okay. And this charter</p> <p>11 indicates that you were on the SOM steering</p> <p>12 committee.</p> <p>13 A. Yes.</p> <p>14 Q. And that you attended meetings</p> <p>15 once per quarter. Is that correct?</p> <p>16 MR. BERG: Object to form.</p> <p>17 A. Yes.</p> <p>18 QUESTIONS BY MS. KEECH:</p> <p>19 Q. Okay. So --</p> <p>20 A. I'm sorry. It indicates that</p> <p>21 there were steering committee meetings with a</p> <p>22 frequency of once per quarter and that I was</p> <p>23 a member of the steering committee. It</p> <p>24 doesn't really give any kind of indication</p> <p>25 whether I was in attendance.</p>
<p>1 Q. Any in customer service?</p> <p>2 A. Not that I recall.</p> <p>3 Q. Okay. Are you familiar with</p> <p>4 the term "30-day cumulative increase</p> <p>5 trigger"?</p> <p>6 A. No.</p> <p>7 Q. Were you at all involved in the</p> <p>8 formula involved in the Suspicious Order</p> <p>9 Monitoring program?</p> <p>10 MR. BERG: Object to form.</p> <p>11 A. No.</p> <p>12 QUESTIONS BY MS. KEECH:</p> <p>13 Q. Do you know who Mansfield is?</p> <p>14 A. Mansfield is a town in</p> <p>15 Massachusetts where Covidien had offices.</p> <p>16 Q. Okay. You can set that aside.</p> <p>17 (Mallinckrodt-Saffold Exhibit 9</p> <p>18 was marked for identification.)</p> <p>19 QUESTIONS BY MS. KEECH:</p> <p>20 Q. I'm handing you what has been</p> <p>21 marked as Exhibit 9, bearing Bates number</p> <p>22 MNK-T1_000496062.</p> <p>23 Do you recognize this document?</p> <p>24 A. No.</p> <p>25 Q. Any reason to doubt its</p>	<p>Page 79</p> <p>1 Q. Okay. Did you attend meetings</p> <p>2 for this Suspicious Order Monitoring team?</p> <p>3 A. I believe so. I don't recall</p> <p>4 like a specific meeting, but...</p> <p>5 Q. Did you receive communications</p> <p>6 regarding the Suspicious Order Monitoring</p> <p>7 team?</p> <p>8 A. Yes.</p> <p>9 Q. Did you participate in any way?</p> <p>10 A. No.</p> <p>11 Q. So how would you describe your</p> <p>12 role as a steering committee member?</p> <p>13 A. I really can't recall doing</p> <p>14 much as a steering committee member, so I</p> <p>15 would say it was peripheral.</p> <p>16 Q. Were you familiar with the</p> <p>17 process description of the Suspicious Order</p> <p>18 Monitoring team?</p> <p>19 MR. BERG: Object to form.</p> <p>20 A. Yes.</p> <p>21 QUESTIONS BY MS. KEECH:</p> <p>22 Q. Can you read the process</p> <p>23 description on this document?</p> <p>24 A. "Maintain regulatory compliance</p> <p>25 with DEA mandated Suspicious Order Monitoring</p>

<p style="text-align: right;">Page 82</p> <p>1 (SOM) as stated in 21 C.F.R. 1301.74(b). 2 Upgrade Mallinckrodt's existing SOM program 3 to meet/exceed DEA requirements and to adapt 4 program based upon changing trends in 5 diversion and abuse of controlled 6 substances."</p> <p>7 Q. Thank you. 8 So as a steering committee 9 member, were you aware of the DEA 10 requirements for developing an SOM? 11 A. No. And -- no. 12 (Mallinckrodt-Saffold 13 Exhibit 10 was marked for 14 identification.)</p> <p>15 QUESTIONS BY MS. KEECH: 16 Q. I'm now handing you what has 17 been marked as Exhibit 10, bearing Bates 18 number MNK-T1_000496098. 19 A. Thank you. 20 Q. And this document is the 21 Mallinckrodt Controlled Substance Suspicious 22 Order Monitoring Program, Presentation for 23 Marketing Group dated March 21st, 2011. 24 Are you familiar with this 25 document?</p>	<p style="text-align: right;">Page 84</p> <p>1 Q. And Karen Harper was the team 2 leader? Is that correct? 3 A. Yes. 4 Q. What was your working 5 relationship with Karen Harper, if any? 6 A. So we were colleagues. 7 Q. Okay. 8 A. At times, we did report to the 9 same boss, and really, my relationship with 10 Karen was what Karen says we need to do, we 11 need to do, right. So we listen to Karen. 12 Q. And Jim Rausch was your direct 13 report, correct? 14 A. Yes. 15 Q. Okay. Do you know who 16 generated this PowerPoint? 17 A. No. 18 Q. Can you please turn your 19 attention to page 2 of the PowerPoint. This 20 is difficult to read. It's difficult to see 21 on the paper, but I can represent to you that 22 it reads: Perry Moore, the executive 23 producer of the Chronicles of Narnia movies, 24 was found dead in his New York apartment 25 Thursday, February 17th, 2011, after an</p>
<p style="text-align: right;">Page 83</p> <p>1 A. No. 2 Q. Any reason to doubt its 3 authenticity? 4 A. No. 5 Q. Can you please turn with me to 6 page 4 of the document. 7 A. Sure. 8 Q. This lists you and Jim Rausch 9 as the SOM representatives from the customer 10 service department, correct? 11 A. I think it lists us as members 12 of the procedure team. 13 Q. And were you a member of the 14 procedure team? 15 A. Yes. 16 Q. Okay. Did you have any other 17 roles on the SOM team? 18 A. Not that I can recall. 19 Q. Can you describe your role as a 20 member of the procedure team? 21 A. I really don't recall what I 22 did as a member of the procedure team. 23 Q. Do you know how team members 24 were selected? 25 A. No.</p>	<p style="text-align: right;">Page 85</p> <p>1 apparent overdose, reports the New York Daily 2 News. 3 The 39-year-old producer was 4 found in the bathroom around 9:30 a.m. by 5 partner Hunter Hill. Moore's father, Bill, 6 tells the Daily News, "We're in shock. He 7 was in a great, great mood when we spoke with 8 him the night before. No one was expecting 9 this."</p> <p>10 Were you aware that people were 11 dying from prescription drug overdoses? 12 MR. BERG: Object to form. 13 A. Yes. 14 QUESTIONS BY MS. KEECH: 15 Q. Okay. And please turn with me 16 to page 6 of this document. And this 17 addresses DEA policy on suspicious orders. 18 Were you aware of these 19 requirements? 20 MR. BERG: Object to form. 21 A. Yes. 22 QUESTIONS BY MS. KEECH: 23 Q. So you were aware of 24 Mallinckrodt's obligations to design and 25 operate a Suspicious Order Monitoring system?</p>

Page 86	Page 88
<p>1 MR. BERG: Object to form.</p> <p>2 A. Yes.</p> <p>3 QUESTIONS BY MS. KEECH:</p> <p>4 Q. Okay. Can you turn with me to</p> <p>5 page 8. This contains an image of a 2007</p> <p>6 letter sent from the DEA.</p> <p>7 Do you recognize this letter?</p> <p>8 MR. BERG: Object to form.</p> <p>9 A. No.</p> <p>10 QUESTIONS BY MS. KEECH:</p> <p>11 Q. Never seen it before?</p> <p>12 A. I wouldn't say I've never seen</p> <p>13 it before. I certainly don't recognize it,</p> <p>14 and I guess I'd point out that I'm just</p> <p>15 looking at the date of this letter and it was</p> <p>16 certainly prior to me even working in any</p> <p>17 controlled substances at Mallinckrodt.</p> <p>18 Q. Okay. But when you began</p> <p>19 working in customer service in 2009, did</p> <p>20 anyone discuss this letter with you?</p> <p>21 A. I think as part of the</p> <p>22 training, you know, the requirements that the</p> <p>23 letter seemed to indicate, yes.</p> <p>24 Q. Okay.</p> <p>25 A. So I wouldn't -- but I can't</p>	<p>1 Q. Are you familiar with those?</p> <p>2 MR. BERG: Object to form.</p> <p>3 A. Am I familiar with the</p> <p>4 distributors?</p> <p>5 QUESTIONS BY MS. KEECH:</p> <p>6 Q. Correct.</p> <p>7 A. Yes.</p> <p>8 Q. And were you aware of each of</p> <p>9 these disciplinary actions against them?</p> <p>10 A. Yes, in terms of I've seen kind</p> <p>11 of this slide in my training, but no in terms</p> <p>12 of like what was -- you know, any details.</p> <p>13 Q. So turning to page 15, this</p> <p>14 references the DEA's St. Louis conversation</p> <p>15 from July 20th, 2010. The third line down</p> <p>16 indicates Mallinckrodt is viewed as the</p> <p>17 kingpin within the drug cartel.</p> <p>18 What does that mean to you?</p> <p>19 MR. BERG: Object to form.</p> <p>20 A. I don't know. I don't recall</p> <p>21 ever hearing or anything intimated like that</p> <p>22 before.</p> <p>23 QUESTIONS BY MS. KEECH:</p> <p>24 Q. Is this the first time that</p> <p>25 you've heard Mallinckrodt referred to as the</p>
<p>1 really recall discussing this letter.</p> <p>2 Q. Do you recall whether your</p> <p>3 training discussed whether Mallinckrodt was</p> <p>4 required to inform the local DEA diversion</p> <p>5 office of suspicious orders when they were</p> <p>6 discovered?</p> <p>7 A. Yes.</p> <p>8 Q. And were you aware that the DEA</p> <p>9 could immediately suspend or revoke</p> <p>10 registration for violations of the Controlled</p> <p>11 Substances Act?</p> <p>12 A. Yes.</p> <p>13 Q. Were you aware of distributors</p> <p>14 who got into trouble with the DEA?</p> <p>15 MR. BERG: Object to form.</p> <p>16 A. Yes.</p> <p>17 QUESTIONS BY MS. KEECH:</p> <p>18 Q. Okay. So please turn with me</p> <p>19 to page 9. This indicates the DEA suspends</p> <p>20 the licenses of distributors for not</p> <p>21 maintaining effective controls -- effective</p> <p>22 controls against diversion of controlled</p> <p>23 substances, and then it lists three</p> <p>24 distributors.</p> <p>25 A. Uh-huh.</p>	<p>1 kingpin within the drug cartel?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. Would you agree with</p> <p>4 that characterization?</p> <p>5 A. No.</p> <p>6 Q. If you'll turn with me to</p> <p>7 page 17, this image appears to be a</p> <p>8 photograph taken from inside of a vehicle of</p> <p>9 individuals lined up outside.</p> <p>10 Are you familiar with this</p> <p>11 photo?</p> <p>12 A. I don't recall. I don't</p> <p>13 think -- I'm not familiar with it, no.</p> <p>14 Q. Do you know what this photo</p> <p>15 represents --</p> <p>16 MR. BERG: Object to form.</p> <p>17 A. No.</p> <p>18 QUESTIONS BY MS. KEECH:</p> <p>19 Q. -- if anything?</p> <p>20 Do you know what, if anything,</p> <p>21 is the significance of this photo?</p> <p>22 MR. BERG: Object to form.</p> <p>23 A. No.</p> <p>24 QUESTIONS BY MS. KEECH:</p> <p>25 Q. Do you know why it was included</p>

Page 90	Page 92
<p>1 in the PowerPoint?</p> <p>2 MR. BERG: Object to form.</p> <p>3 A. No.</p> <p>4 QUESTIONS BY MS. KEECH:</p> <p>5 Q. On the next page, 18, there is</p> <p>6 another image. What does that appear to be</p> <p>7 of?</p> <p>8 A. I don't know what this is. It</p> <p>9 looks like a window with -- I mean, I can</p> <p>10 only describe the picture. It says, "Leave</p> <p>11 prescription here," and there's a window and</p> <p>12 there's signs and there's a sign that says,</p> <p>13 "No cell phone use in pharmacy," so I'm</p> <p>14 guessing it's either a window into or out of</p> <p>15 a pharmacy.</p> <p>16 Q. And do you see the sign that</p> <p>17 reads, "We do not accept any insurance on</p> <p>18 oxycodone products by Mallinckrodt or</p> <p>19 Actavis"? Lower left.</p> <p>20 A. I do, yes.</p> <p>21 Q. Any idea why this photo may</p> <p>22 have been included in the PowerPoint?</p> <p>23 MR. BERG: Object to form.</p> <p>24 A. No.</p> <p>25 QUESTIONS BY MS. KEECH:</p>	<p>1 A. Yes.</p> <p>2 QUESTIONS BY MS. KEECH:</p> <p>3 Q. Okay. And after or sometime</p> <p>4 during 2010, the -- did the SOM program</p> <p>5 change?</p> <p>6 A. I don't remember.</p> <p>7 Q. Do you remember whether it</p> <p>8 changed?</p> <p>9 A. Yes. I mean, there were</p> <p>10 changes.</p> <p>11 Q. Okay.</p> <p>12 A. You know, the timing of</p> <p>13 changes, kind of a constant, continuous</p> <p>14 improvement process, so I'm not sure -- you</p> <p>15 know, I couldn't really be assigned any time</p> <p>16 frame for a particular change nor, you know,</p> <p>17 characterize any change.</p> <p>18 Q. Okay. Are you aware of whether</p> <p>19 there was ever a shift away from the customer</p> <p>20 service manager reviewing orders in the new</p> <p>21 SOM program?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And do you know when</p> <p>24 that occurred?</p> <p>25 A. No.</p>
<p>Page 91</p> <p>1 Q. And page 23 of the PowerPoint</p> <p>2 shows an eBay bid for empty Mallinckrodt</p> <p>3 bottles. Are you aware of a legitimate</p> <p>4 reason why someone would want to purchase</p> <p>5 empty Mallinckrodt bottles?</p> <p>6 A. No.</p> <p>7 Q. Do you agree that this</p> <p>8 advertisement is evidence of diversion or</p> <p>9 attempted diversion?</p> <p>10 MR. BERG: Object to form.</p> <p>11 A. I'm not a diversion person,</p> <p>12 so...</p> <p>13 QUESTIONS BY MS. KEECH:</p> <p>14 Q. Okay. Let's turn back to</p> <p>15 page 13 of this document. This indicates</p> <p>16 that it was the existing SOM program prior to</p> <p>17 June 2010. Take a moment to review this</p> <p>18 slide.</p> <p>19 (Document review by witness.)</p> <p>20 A. Okay.</p> <p>21 QUESTIONS BY MS. KEECH:</p> <p>22 Q. Okay. Is this consistent with</p> <p>23 your understanding of what the SOM program</p> <p>24 process was prior to June of 2010?</p> <p>25 MR. BERG: Object to form.</p>	<p>Page 93</p> <p>1 Q. Do you know why there was a</p> <p>2 shift from customer service reviewing orders?</p> <p>3 A. No.</p> <p>4 Q. Were you aware of whether there</p> <p>5 was ever any concern expressed by the DEA</p> <p>6 regarding a potential conflict of interest in</p> <p>7 customer service regulating but having a</p> <p>8 conflicting interest?</p> <p>9 MR. BERG: Object to form.</p> <p>10 A. No.</p> <p>11 QUESTIONS BY MS. KEECH:</p> <p>12 Q. Do you personally believe there</p> <p>13 is a conflict of interest in being involved</p> <p>14 in customer service and also having customer</p> <p>15 service regulate suspicious orders?</p> <p>16 MR. BERG: Object to form.</p> <p>17 A. No, absolutely not. So to give</p> <p>18 service, there's no service without</p> <p>19 compliance. So it was in our interest to</p> <p>20 comply.</p> <p>21 MR. BERG: How you doing? Do</p> <p>22 you want to take a quick break?</p> <p>23 THE WITNESS: Yeah, why don't</p> <p>24 we take a break.</p> <p>25 MR. BERG: Is that okay?</p>

Page 94	Page 96
<p>1 MS. KEECH: Sure. Yeah, that's 2 fine.</p> <p>3 THE VIDEOGRAPHER: Off the 4 record at 11:14.</p> <p>5 (Recess taken, 11:14 a.m. to 6 11:27 a.m.)</p> <p>7 THE VIDEOGRAPHER: All right, 8 stand by. The time is 11:27. Back on 9 the record, beginning of File 2.</p> <p>10 QUESTIONS BY MS. KEECH:</p> <p>11 Q. Are you aware of whether 12 Mallinckrodt ever sold empty pill bottles?</p> <p>13 A. No.</p> <p>14 Q. Do you recall anyone ever 15 discussing why having empty pill bottles on 16 the market would be problematic?</p> <p>17 MR. BERG: Object to form.</p> <p>18 A. No.</p> <p>19 QUESTIONS BY MS. KEECH:</p> <p>20 Q. Ever recall any discussion 21 about empty pill bottles in general?</p> <p>22 A. No.</p> <p>23 Q. Okay. As part of any of your 24 trainings at Mallinckrodt, do you recall ever 25 watching a presentation that included video</p>	<p>1 the specifics surrounding this specific one, 2 right.</p> <p>3 Q. Sure.</p> <p>4 And how many direct reports did 5 you have?</p> <p>6 A. At the time of -- are you --</p> <p>7 Q. In 2009.</p> <p>8 A. In 2009? Jim, Cathy... I'd say 9 six, I believe.</p> <p>10 Q. Okay. Do you remember who they 11 were?</p> <p>12 A. Tanisha Hicks, manager of 13 respiratory and monitoring solutions; Jim 14 Rausch, manager of -- I think he was dosage 15 like by July 1, I think he was dosage; Cathy 16 Stewart, manager of API; Charity Aranda was a 17 customer service analyst; Doris Bonds, she 18 was my administrative assistant; and I can't 19 remember, I may have had others, but I can't 20 be sure.</p> <p>21 Q. Okay. And did you require each 22 of your direct reports, excluding your 23 assistant, to provide you monthly reports?</p> <p>24 A. Yes.</p> <p>25 Q. Did you yourself author a</p>
<p>1 footage of individuals standing outside of a 2 pill mill?</p> <p>3 A. No.</p> <p>4 Q. Ever recall hearing about such 5 a video?</p> <p>6 A. No.</p> <p>7 Q. Do you remember anyone ever 8 discussing such a video?</p> <p>9 A. No.</p> <p>10 Q. Okay.</p> <p>11 (Mallinckrodt-Saffold 12 Exhibit 11 was marked for 13 identification.)</p> <p>14 QUESTIONS BY MS. KEECH:</p> <p>15 Q. I'm handing you what has been 16 marked as Exhibit 11, bearing Bates number 17 MNK-T1_0000303583. This is a Pharmaceutical 18 Logistics Monthly Report dated July 1st, 19 2009, addressed to you from Jim Rausch.</p> <p>20 Do you recognize this document?</p> <p>21 A. Yes. Like in terms of like 22 that this is something I required my direct 23 reports to give me.</p> <p>24 Q. Okay.</p> <p>25 A. But, you know, I don't recall</p>	<p>1 monthly report?</p> <p>2 A. At this time, yes.</p> <p>3 Q. Okay. And who did that report 4 go to?</p> <p>5 A. To my supervisor, so that would 6 have been JoAnne Levy, the VP of logistics at 7 this time.</p> <p>8 Q. And what was the content of the 9 reports that you authored?</p> <p>10 A. In a pretty rigid format, so it 11 would have been -- it starts out with HR, and 12 then budget, kind of my head count, and then 13 development, you know, for people and any 14 other personnel highlights and maybe 15 lowlights.</p> <p>16 Then from there, I usually went 17 into performance on IO, our individual 18 objective performance. So, you know, hey, I 19 know I'm supposed to be doing this, this and 20 this, here's where we are. And then 21 following that was usually like a project, so 22 here's some projects I'm on and here's their 23 status.</p> <p>24 And then following that, issues 25 or miscellaneous, and that's pretty much my</p>

Page 98	Page 100
<p>1 format I've always used.</p> <p>2 Q. Do you know whether your</p> <p>3 monthly reports were ever submitted to the</p> <p>4 DEA?</p> <p>5 A. No.</p> <p>6 Q. Did customer service, in</p> <p>7 general, submit monthly reports to anyone?</p> <p>8 MR. BERG: Object to form.</p> <p>9 A. I'm sorry. Can you repeat that</p> <p>10 question?</p> <p>11 QUESTIONS BY MS. KEECH:</p> <p>12 Q. Sure.</p> <p>13 Did customer service, in</p> <p>14 general, submit a monthly report</p> <p>15 summarizing --</p> <p>16 MR. BERG: Object to form.</p> <p>17 A. To anyone?</p> <p>18 QUESTIONS BY MS. KEECH:</p> <p>19 Q. To anyone.</p> <p>20 A. No. Not like an overall</p> <p>21 customer service report, no.</p> <p>22 Q. Okay. Do you know whether</p> <p>23 Mallinckrodt, in general, submitted monthly</p> <p>24 reports to the DEA?</p> <p>25 A. No.</p>	<p>1 daily suspicious order report, but I'm not</p> <p>2 sure about the specific concern he's talking</p> <p>3 about, right.</p> <p>4 Q. And what was the daily</p> <p>5 suspicious order report?</p> <p>6 A. So I think that's a bit of a</p> <p>7 misnomer in his report. I think there was a</p> <p>8 report that was a peculiar order report, and</p> <p>9 then parameters were set and then the report</p> <p>10 would get generated and Jim was one of the</p> <p>11 recipients of this report. And then he</p> <p>12 worked -- and so that's kind of what it is,</p> <p>13 I guess.</p> <p>14 Q. Okay. And who was the peculiar</p> <p>15 order report sent to?</p> <p>16 A. I'm not sure everyone who it</p> <p>17 was sent to.</p> <p>18 Q. Do you know --</p> <p>19 A. I know Cathy and Jim, I</p> <p>20 believe, both received it.</p> <p>21 Q. Did you ever receive the</p> <p>22 peculiar order report?</p> <p>23 A. I can't recall ever getting it.</p> <p>24 Q. So just to clarify, part of</p> <p>25 your job was to supervise Jim Rausch, who</p>
<p style="text-align: center;">Page 99</p> <p>1 Q. And what was the content of the</p> <p>2 reports that your direct reports generated?</p> <p>3 A. Well, it was a little variable.</p> <p>4 Like if you look at this one, it's not a</p> <p>5 great one, so it's just some personal</p> <p>6 highlights and then some business support</p> <p>7 highlights. And it's just like a lot of</p> <p>8 stuff, right.</p> <p>9 Others might be a little bit</p> <p>10 more on performance or metrics, so it just,</p> <p>11 you know, kind of varied, and as you coached</p> <p>12 people to give you better reports, they would</p> <p>13 give you better ones.</p> <p>14 Q. Okay. So turning to this</p> <p>15 exhibit under API Business Support Highlights</p> <p>16 in the first paragraph, Jim writes: There is</p> <p>17 concern on how time-consuming the daily</p> <p>18 suspicious order report might be for customer</p> <p>19 service to monitor on a daily basis.</p> <p>20 Are you familiar with what he</p> <p>21 was referring to there?</p> <p>22 A. No.</p> <p>23 Q. So you're not aware of what a</p> <p>24 daily suspicious order report was?</p> <p>25 A. So I am familiar with what -- a</p>	<p style="text-align: center;">Page 101</p> <p>1 received the peculiar order reports, correct?</p> <p>2 A. Correct.</p> <p>3 Q. But you never personally</p> <p>4 received the reports?</p> <p>5 MR. BERG: Object to form.</p> <p>6 A. Correct. Or at least I don't</p> <p>7 recall receiving these reports.</p> <p>8 QUESTIONS BY MS. KEECH:</p> <p>9 Q. So how were you monitoring</p> <p>10 whether he was in compliance with his stated</p> <p>11 goal with regard to the SOM --</p> <p>12 MR. BERG: Object to form.</p> <p>13 QUESTIONS BY MS. KEECH:</p> <p>14 Q. -- program?</p> <p>15 A. Can you repeat that? How was I</p> <p>16 monitoring what?</p> <p>17 Q. How were you monitoring whether</p> <p>18 Jim was meeting his goals with regard to the</p> <p>19 SOM program if you also -- if you were not</p> <p>20 receiving the suspicious or peculiar order</p> <p>21 reports?</p> <p>22 MR. BERG: Object to form.</p> <p>23 A. Well, I think the primary way</p> <p>24 would be from our compliance team would be</p> <p>25 telling me he's not doing what we need him to</p>

Page 102	Page 104
<p>1 do.</p> <p>2 QUESTIONS BY MS. KEECH:</p> <p>3 Q. So you were relying on</p> <p>4 compliance to tell you whether Jim was</p> <p>5 satisfying his goals?</p> <p>6 MR. BERG: Object to form.</p> <p>7 A. I was relying on compliance to</p> <p>8 tell me whether or not Jim was satisfying his</p> <p>9 goals regarding compliance, yes.</p> <p>10 QUESTIONS BY MS. KEECH:</p> <p>11 Q. What were other -- Jim's other</p> <p>12 stated goals outside of compliance?</p> <p>13 A. I don't know. I don't recall</p> <p>14 all his goals.</p> <p>15 Q. Did he have others other than</p> <p>16 the one that we discussed earlier?</p> <p>17 A. You know, I don't recall, but</p> <p>18 it would be safe to say yes.</p> <p>19 Q. Do you know whether this daily</p> <p>20 suspicious order report was switched away</p> <p>21 from customer service?</p> <p>22 MR. BERG: Object to form.</p> <p>23 A. I don't know if the report</p> <p>24 itself was ever switched away from customer</p> <p>25 service, no, I don't know.</p>	<p>1 It indicates: We missed the</p> <p>2 ship date on this order a couple of times.</p> <p>3 A. Okay.</p> <p>4 Q. It says: We missed the 6/1</p> <p>5 ship date because label delay, containers</p> <p>6 were dirtier and more damaged than normal,</p> <p>7 and there was water coming from the weep</p> <p>8 holes on the bottom of the containers.</p> <p>9 Customer service was not notified of this</p> <p>10 until 6/2, the day after it was supposed to</p> <p>11 have shipped. Marketing was very upset on</p> <p>12 this one.</p> <p>13 Is this the type of information</p> <p>14 that was shared with customer service?</p> <p>15 MR. BERG: Object to form.</p> <p>16 A. Well, I'm not sure I</p> <p>17 understand, like what type of information --</p> <p>18 I mean, you're -- this is just an incident</p> <p>19 that happened.</p> <p>20 QUESTIONS BY MS. KEECH:</p> <p>21 Q. Right. So generally speaking,</p> <p>22 would this type of incident be reported to</p> <p>23 customer service?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. And would customer</p>
<p style="text-align: center;">Page 103</p> <p>1 QUESTIONS BY MS. KEECH:</p> <p>2 Q. So Jim brought up this concern</p> <p>3 of how time-consuming the daily suspicious</p> <p>4 order report might be for customer service to</p> <p>5 monitor on a daily basis.</p> <p>6 As his supervisor, what, if</p> <p>7 anything, did you do after receiving this</p> <p>8 information?</p> <p>9 A. I can't recall doing anything.</p> <p>10 I mean, this is -- it's kind of like an FYI.</p> <p>11 Hey, we're gonna run it, test it and see.</p> <p>12 Q. And he was expressing that it</p> <p>13 was time-consuming?</p> <p>14 A. No, I don't think he was. I</p> <p>15 think he was expressing that he was concerned</p> <p>16 it was and he was going to address those</p> <p>17 concerns by testing it.</p> <p>18 Q. Okay.</p> <p>19 A. And so that's it.</p> <p>20 Q. Do you know what, if anything,</p> <p>21 the outcome of his testing was?</p> <p>22 A. No.</p> <p>23 Q. Please turn with me to the</p> <p>24 second page, second paragraph, beginning with</p> <p>25 "Ohm Labs."</p>	<p style="text-align: center;">Page 105</p> <p>1 service then communicate this type of</p> <p>2 incident to any other department within</p> <p>3 Mallinckrodt?</p> <p>4 A. Yes, or -- but typically when</p> <p>5 we're finding this out, usually others are</p> <p>6 aware of it too, sometimes even before us.</p> <p>7 Yes, so...</p> <p>8 Q. Okay. And what other groups</p> <p>9 within Mallinckrodt would customer service</p> <p>10 share this type of information with?</p> <p>11 A. Well, certainly the shipping</p> <p>12 and manufacturing folks, if they weren't</p> <p>13 aware, the leadership there; planning; sales,</p> <p>14 you know, the sales rep, I'd think you'd want</p> <p>15 to let him know; and then marketing,</p> <p>16 probably.</p> <p>17 Q. Okay. Was customer service</p> <p>18 also notified if there was tampering or</p> <p>19 suspected tampering issues, for example, if</p> <p>20 product was missing from a container?</p> <p>21 A. We could be, yes.</p> <p>22 Q. Okay. And were you ever</p> <p>23 notified of such tampering issues?</p> <p>24 A. Yes.</p> <p>25 Q. How quickly were these</p>

Page 106	Page 108
<p>1 incidents reported within Mallinckrodt?</p> <p>2 A. Really quickly.</p> <p>3 Q. Were there ever delays in</p> <p>4 reporting?</p> <p>5 A. Not that I recall.</p> <p>6 Q. Do you recall ever reporting</p> <p>7 such tampering issues to the DEA?</p> <p>8 A. No. I typically didn't report</p> <p>9 anything. But my team, like my -- you know,</p> <p>10 the first person who hears about this would</p> <p>11 be a customer service agent, and he or she</p> <p>12 would then report to a compliance person,</p> <p>13 really fast, was kind of the goal.</p> <p>14 Q. Were you CC'd on those</p> <p>15 communications or copied?</p> <p>16 A. I don't recall. It's likely I</p> <p>17 was, but the main vehicle for doing that, I</p> <p>18 wasn't -- they used like a share file to put</p> <p>19 the information in.</p> <p>20 Q. Were there any checks to ensure</p> <p>21 that customer service agents were in fact</p> <p>22 reporting these issues to Mallinckrodt</p> <p>23 compliance?</p> <p>24 A. I don't know. I would think</p> <p>25 compliance would be checking that.</p>	<p>1 earlier today. What is a 222 form?</p> <p>2 A. So not being a compliance</p> <p>3 expert, and I don't know if I can give you a</p> <p>4 great definition of it, but in practice, a</p> <p>5 form -- 222 form would accompany an order,</p> <p>6 and it demonstrated that one was allowed to</p> <p>7 purchase the compound or the molecule as well</p> <p>8 as the quantity.</p> <p>9 Q. Are you aware whether a 222</p> <p>10 form was an official form from the DEA?</p> <p>11 A. Yes, it is an official form.</p> <p>12 Q. And was it required for every</p> <p>13 distribution, purchase or transfer of a</p> <p>14 Schedule II controlled substance?</p> <p>15 MR. BERG: Object to form.</p> <p>16 A. No. I'm not a compliance</p> <p>17 expert, but in addition to a 222 form, the</p> <p>18 DEA has Controlled Substance Ordering System,</p> <p>19 sometimes referred to as CSOS, and then those</p> <p>20 wouldn't have 222 forms because they're</p> <p>21 electronic and a 222 form is paper.</p> <p>22 QUESTIONS BY MS. KEECH:</p> <p>23 Q. Okay. Based on your</p> <p>24 understanding of a 222 form, is a portion of</p> <p>25 the form filled out by the purchaser and</p>
<p style="text-align: center;">Page 107</p> <p>1 Q. Okay. Did customer service</p> <p>2 agents also identify peculiar orders that</p> <p>3 then they communicated to compliance?</p> <p>4 A. I don't believe so.</p> <p>5 Q. So who at Mallinckrodt, if</p> <p>6 anyone, was monitoring orders to determine</p> <p>7 whether they were peculiar or suspicious?</p> <p>8 A. Well, so my understanding of</p> <p>9 the Suspicious Order Monitoring program is</p> <p>10 that the compliance team owns the program and</p> <p>11 then they set the parameters, which were</p> <p>12 largely system-driven.</p> <p>13 Q. What do you mean by that?</p> <p>14 A. So they set the parameters of</p> <p>15 like what a definition of a suspicious order</p> <p>16 would be and then the system could run edits</p> <p>17 and checks against that and then an order</p> <p>18 could be flagged as peculiar -- and I don't</p> <p>19 know if that's the only type of flag -- and</p> <p>20 then would be able to be investigated.</p> <p>21 So that monitoring part is</p> <p>22 really, you know, all orders being reviewed</p> <p>23 and then, you know, filtered out through this</p> <p>24 report.</p> <p>25 Q. You mentioned a 222 form</p>	<p style="text-align: center;">Page 109</p> <p>1 another portion filled out by the supplier?</p> <p>2 A. Yes.</p> <p>3 Q. Does it include the drug code,</p> <p>4 supplier's DEA registration number and the</p> <p>5 number of packages shipped and the date of</p> <p>6 shipment?</p> <p>7 MR. BERG: Object to form.</p> <p>8 A. I don't think I could tell you</p> <p>9 exactly what's on the form.</p> <p>10 QUESTIONS BY MS. KEECH:</p> <p>11 Q. Okay.</p> <p>12 (Mallinckrodt-Saffold</p> <p>13 Exhibit 12 was marked for</p> <p>14 identification.)</p> <p>15 QUESTIONS BY MS. KEECH:</p> <p>16 Q. I'm handing you what has been</p> <p>17 marked as Exhibit 12. This is bearing Bates</p> <p>18 number MNK-T1_0000302318.</p> <p>19 Do you recognize this document?</p> <p>20 A. Yes.</p> <p>21 Q. And what is it?</p> <p>22 A. This is a monthly report</p> <p>23 written by me.</p> <p>24 Q. To your supervisor, JoAnne</p> <p>25 Levy?</p>

Page 110	Page 112
<p>1 A. Yes.</p> <p>2 Q. And is this the type of report</p> <p>3 that we discussed earlier that you generated</p> <p>4 on a monthly basis?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. If you'll turn with me</p> <p>7 to the last page of the report, under the</p> <p>8 heading Specialty Pharmaceutical Products,</p> <p>9 you wrote that the time to clear 222 forms</p> <p>10 was improved from several days to 1 day.</p> <p>11 Can you describe the process</p> <p>12 for me involved in clearing a 222 form?</p> <p>13 A. Not with any confidence.</p> <p>14 Q. So who was responsible for</p> <p>15 clearing 222 forms?</p> <p>16 A. Customer service agents.</p> <p>17 Q. So as their supervisor, you did</p> <p>18 not know what customer service agents did to</p> <p>19 clear 222 forms?</p> <p>20 MR. BERG: Object to form.</p> <p>21 A. Not at the level to be able to</p> <p>22 describe the process.</p> <p>23 QUESTIONS BY MS. KEECH:</p> <p>24 Q. Okay. Can you describe the</p> <p>25 purpose?</p>	<p>1 Q. And who was responsible for</p> <p>2 that?</p> <p>3 A. Well, I'm sorry, who was</p> <p>4 responsible for making sure the forms were</p> <p>5 filled out? So the customer service agents</p> <p>6 had to fill them out and then the compliance</p> <p>7 team was the ones who really made sure they</p> <p>8 were perfect.</p> <p>9 Q. Are you aware of any errors</p> <p>10 ever being on DEA 222 forms at Mallinckrodt?</p> <p>11 A. Yes.</p> <p>12 Q. And do you know whether all of</p> <p>13 those were reported to the DEA?</p> <p>14 MR. BERG: Object to form.</p> <p>15 A. I'm not sure. I'm -- you know,</p> <p>16 any error I was ever made aware of,</p> <p>17 absolutely, yes.</p> <p>18 QUESTIONS BY MS. KEECH:</p> <p>19 Q. Okay.</p> <p>20 (Mallinckrodt-Saffold</p> <p>21 Exhibit 13 was marked for</p> <p>22 identification.)</p> <p>23 QUESTIONS BY MS. KEECH:</p> <p>24 Q. I'm handing you what's been</p> <p>25 marked as Exhibit 13, bearing Bates stamp</p>
<p style="text-align: center;">Page 111</p> <p>1 A. Yes. The purpose of clearing a</p> <p>2 222 form was to report the sale and track the</p> <p>3 sale.</p> <p>4 Q. So any idea of what occurred</p> <p>5 when someone was clearing a 222 form?</p> <p>6 A. Not like specifically. So they</p> <p>7 would, you know, work the form after an order</p> <p>8 shipped and make sure that things -- you</p> <p>9 know, the fields were indicated, right, and</p> <p>10 they would take the forms and make sure those</p> <p>11 went to our DEA compliance team for record</p> <p>12 retention. And I think -- I don't know what</p> <p>13 our compliance team did with them afterwards.</p> <p>14 Q. So this indicates the process</p> <p>15 previously took several days, and then</p> <p>16 indicates that it was shifted to one day.</p> <p>17 A. Yes.</p> <p>18 Q. Was there an emphasis placed on</p> <p>19 timing or completing these forms?</p> <p>20 A. I'm not sure. I don't really</p> <p>21 recall.</p> <p>22 Q. Did anyone at Mallinckrodt</p> <p>23 emphasize ensuring that the forms are</p> <p>24 properly filled out?</p> <p>25 A. Yes.</p>	<p style="text-align: center;">Page 113</p> <p>1 MNK-T1_000280653.</p> <p>2 Do you recognize this document?</p> <p>3 A. Yes.</p> <p>4 Q. And what is it?</p> <p>5 A. It's a monthly report.</p> <p>6 Q. Similar to the report we just</p> <p>7 discussed?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And this time it was</p> <p>10 sent to Mike Santowski. Is that correct?</p> <p>11 A. Yes.</p> <p>12 Q. Who was Mike Santowski?</p> <p>13 A. He was my supervisor on that</p> <p>14 date.</p> <p>15 Q. Okay. And this was dated</p> <p>16 November 2nd, 2010, reporting on October</p> <p>17 monthly sales from 2010? Is that correct?</p> <p>18 A. No, it wasn't reporting on</p> <p>19 October monthly sales.</p> <p>20 Q. Or, excuse me. October monthly</p> <p>21 report.</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And under the heading</p> <p>24 Specialty Generics and Specialty Brands, you</p> <p>25 indicate that the peculiar order monitoring</p>

Page 114	Page 116
<p>1 report and process will be moved from 2 customer service to compliance this week. 3 MR. BERG: Object to form. 4 QUESTIONS BY MS. KEECH: 5 Q. Do you recall that? 6 A. No. Like -- no. Like any of 7 the circumstances around it, no. 8 Q. Do you recall that that 9 occurred? 10 A. Yes. 11 Q. Okay. Any reason to doubt that 12 you didn't write that? 13 A. No, I'm pretty sure I did. 14 Q. Do you recall why customer 15 service was shifting responsibility to 16 compliance for the peculiar order monitoring 17 report? 18 A. No. And I guess maybe the 19 characterization that customer service was 20 shifting responsibility to compliance might 21 not be accurate. I would say more 22 compliance, you know, gets to say how we 23 comply, and compliance was saying, eh, we're 24 going to take this over. That's a more fair 25 characterization.</p>	<p>1 A. I can't recall any instance. 2 Q. Do you know or can you describe 3 how Mallinckrodt would determine whether an 4 order flagged as peculiar should be shipped? 5 MR. BERG: Object to form. 6 A. I'm not really familiar with 7 the details at all on how that would occur. 8 QUESTIONS BY MS. KEECH: 9 Q. Okay. Did you ever have any 10 communications with customers that raised any 11 red flags to you about potential abuse or 12 diversion? 13 A. No. 14 Q. And prior to 2011, did you ever 15 recommend that an order be cancelled because 16 you believed it was peculiar or suspicious? 17 A. I don't think so, no. 18 Q. How about after 2011? 19 A. I don't think so either. 20 Q. Okay. So in Exhibit 14, this 21 indicates that in March of 2010, you met with 22 Cathy Stewart, Jim Rausch and Karen Harper to 23 fine-tune the SOM algorithm. 24 A. Uh-huh. 25 Q. Do you recall that meeting?</p>
<p style="text-align: center;">Page 115</p> <p>1 Q. Okay. Do you know why 2 compliance made the decision to take over the 3 peculiar order monitoring? 4 A. No. 5 Q. Do you have any information 6 about the background behind that decision? 7 A. I can't recall any. 8 Q. Do you recall whose idea it 9 was? 10 A. I really can't recall any 11 information. 12 Q. Okay. 13 (Mallinckrodt-Saffold 14 Exhibit 14 was marked for 15 identification.) 16 QUESTIONS BY MS. KEECH: 17 Q. I'm now handing you what's been 18 marked as Exhibit 14, bearing Bates number 19 MNK-T1_000269705. 20 And you were on the SOM 21 steering committee, correct? 22 A. Yes. 23 Q. Did compliance ever consult 24 with you about orders that had been flagged 25 as potentially suspicious or peculiar?</p>	<p style="text-align: center;">Page 117</p> <p>1 A. No. 2 Q. Do you recall working on the 3 SOM algorithm? 4 A. No. 5 Q. Do you know what the SOM 6 algorithm was? 7 A. No. I mean, so, yes, it was an 8 algorithm used to look at orders to help 9 comply with Suspicious Order Monitoring. 10 Q. But no recollection of working 11 on that? 12 A. No. 13 Q. Did you participate at all in 14 generating the reports that were sent to the 15 DEA? 16 A. No. 17 Q. Did you ever see any reports 18 that were sent to the DEA? 19 A. None that I can recall. I'm 20 pretty sure no. 21 Q. Okay. 22 (Mallinckrodt-Saffold 23 Exhibit 15 was marked for 24 identification.) 25 --oOo--</p>

<p style="text-align: right;">Page 118</p> <p>1 QUESTIONS BY MS. KEECH:</p> <p>2 Q. I'm handing you what has been 3 marked as Exhibit 15, bearing Bates number 4 MNK-T1_0000262762. This is an e-mail sent 5 from Jim Rausch to Karen Harper, you were 6 CC'd, on Wednesday, June 9th, 2010, subject 7 line: Suspicious Order Monitoring program. 8 Do you recall receiving this 9 e-mail?</p> <p>10 A. No.</p> <p>11 Q. Any reason to doubt its 12 authenticity?</p> <p>13 A. No.</p> <p>14 Q. Okay. And in this e-mail, Jim 15 Rausch indicates he's not had any orders in 16 the classification of peculiar that have not 17 been cleared and explainable thus far. 18 Are you familiar with the term 19 "peculiar order"?</p> <p>20 MR. BERG: Object to form.</p> <p>21 A. Yes, somewhat.</p> <p>22 QUESTIONS BY MS. KEECH:</p> <p>23 Q. Okay. And how would you define 24 "peculiar order"?</p> <p>25 MR. BERG: Object to form.</p>	<p style="text-align: right;">Page 120</p> <p>1 QUESTIONS BY MS. KEECH:</p> <p>2 Q. Okay. Do you know who within 3 compliance had that role?</p> <p>4 A. No.</p> <p>5 Q. Okay. Do you see, in the first 6 paragraph here, where Jim also writes: Since 7 I don't hold the orders up during my due 8 diligence, it's possible that the order could 9 ship?</p> <p>10 A. Yes.</p> <p>11 Q. Were you familiar with this 12 practice?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And did you find it 15 problematic at all of shipping prior to Jim 16 doing his due diligence?</p> <p>17 A. I really am not compliance, 18 right, so if Karen or anyone in compliance 19 had said it's problematic, then it would be, 20 if they're aware of it, and then I don't find 21 it problematic at all.</p> <p>22 Q. So you just deferred to Karen 23 in compliance?</p> <p>24 A. Yes.</p> <p>25 Q. Did you ever see orders that</p>
<p style="text-align: right;">Page 119</p> <p>1 A. So I'm not sure I can define 2 it. I'm familiar in that orders that were 3 flagged -- were flagged as peculiar based on 4 criteria set by our Suspicious Order 5 Monitoring people in compliance. 6 QUESTIONS BY MS. KEECH:</p> <p>7 Q. Okay. Do you know what that 8 criteria was?</p> <p>9 MR. BERG: Object to form.</p> <p>10 A. No. And I don't know if it 11 ever -- you know, I think it may have changed 12 over a period of time as well, so...</p> <p>13 QUESTIONS BY MS. KEECH:</p> <p>14 Q. Are you familiar with how the 15 term "peculiar order" differed from a 16 suspicious order?</p> <p>17 MR. BERG: Object to form.</p> <p>18 A. No.</p> <p>19 QUESTIONS BY MS. KEECH:</p> <p>20 Q. So who had the authority within 21 Mallinckrodt to determine whether a peculiar 22 order, or order that was identified as either 23 peculiar or suspicious, was okay to ship?</p> <p>24 MR. BERG: Object to form.</p> <p>25 A. Compliance.</p>	<p style="text-align: right;">Page 121</p> <p>1 you believed that were peculiar that were 2 ultimately shipped?</p> <p>3 A. I never -- no, I can't really 4 recall seeing any peculiar orders.</p> <p>5 Q. Were you reviewing the peculiar 6 order reports?</p> <p>7 MR. BERG: Object to form.</p> <p>8 A. I did not review peculiar order 9 reports.</p> <p>10 (Mallinckrodt-Saffold 11 Exhibit 16 was marked for 12 identification.)</p> <p>13 QUESTIONS BY MS. KEECH:</p> <p>14 Q. Okay. I'm handing you what has 15 been marked as Exhibit 16, bearing Bates 16 MNK-T1_0000268194. 17 (Document review by witness.)</p> <p>18 QUESTIONS BY MS. KEECH:</p> <p>19 Q. Are you familiar with this 20 document?</p> <p>21 A. No.</p> <p>22 Q. Okay. This is dated July 30th, 23 2010, from Tiffany Kilper Rowley, subject: 24 DEA Suspicious Order Monitoring program, and 25 your name is listed as one of the required</p>

Page 122	Page 124
<p>1 attendees.</p> <p>2 Do you recall attending this</p> <p>3 meeting?</p> <p>4 A. No.</p> <p>5 Q. Okay. If you'll turn your</p> <p>6 attention to the handwritten note at the</p> <p>7 bottom of this e-mail, it reads: 99% orders</p> <p>8 legit so do not hold orders.</p> <p>9 Were you aware that orders were</p> <p>10 not being held?</p> <p>11 MR. BERG: Object to form.</p> <p>12 QUESTIONS BY MS. KEECH:</p> <p>13 Q. Before a due diligence was</p> <p>14 completed?</p> <p>15 MR. BERG: Object to form.</p> <p>16 A. So I think that's an</p> <p>17 overstatement. Orders could go on hold,</p> <p>18 so -- for a number of reasons. So -- so I'm</p> <p>19 not sure.</p> <p>20 QUESTIONS BY MS. KEECH:</p> <p>21 Q. So Mallinckrodt had the</p> <p>22 capacity to put orders on hold. Is that</p> <p>23 correct?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. But as Jim indicated in</p>	<p>1 MR. BERG: Object to form.</p> <p>2 A. I'm not sure Jim's job was to</p> <p>3 ensure orders were not shipped prior to due</p> <p>4 diligence being performed.</p> <p>5 QUESTIONS BY MS. KEECH:</p> <p>6 Q. How would you describe Jim's</p> <p>7 job?</p> <p>8 A. Jim was supervising the</p> <p>9 customer service team, so he had, you know,</p> <p>10 to manage his employees and then also, you</p> <p>11 know, perform any other activities as</p> <p>12 required, right.</p> <p>13 (Mallinckrodt-Saffold</p> <p>14 Exhibit 17 was marked for</p> <p>15 identification.)</p> <p>16 QUESTIONS BY MS. KEECH:</p> <p>17 Q. I'm handing you what has been</p> <p>18 marked as Exhibit 17, bearing Bates</p> <p>19 MNK-T1_0000262763. This is an e-mail dated</p> <p>20 June 9th, 2010, from Jim Rausch to Karen</p> <p>21 Harper with a CC to you regarding Suspicious</p> <p>22 Order Monitoring program.</p> <p>23 Do you recognize this document?</p> <p>24 A. No.</p> <p>25 Q. Any reason to doubt its</p>
<p style="text-align: center;">Page 123</p> <p>1 his prior e-mail, he did not personally hold</p> <p>2 orders up during his due diligence.</p> <p>3 MR. BERG: Object to form.</p> <p>4 A. Yes.</p> <p>5 QUESTIONS BY MS. KEECH:</p> <p>6 Q. Okay. So if the stated goal of</p> <p>7 the SOM team is to meet or exceed DEA</p> <p>8 expectations, do you believe that this</p> <p>9 practice is consistent with the DEA</p> <p>10 requirements in the stated goals of the SOM</p> <p>11 charter to not complete due diligence before</p> <p>12 shipping an order?</p> <p>13 MR. BERG: Object to form.</p> <p>14 A. I'm not a compliance expert,</p> <p>15 right, so I'm not sure exactly what the</p> <p>16 requirements from the DEA were and wouldn't</p> <p>17 have a good informed opinion on how well it</p> <p>18 met or exceeded.</p> <p>19 QUESTIONS BY MS. KEECH:</p> <p>20 Q. Well, as a supervisor of an</p> <p>21 employee whose job was to ensure that orders</p> <p>22 were not shipped that were peculiar, does it</p> <p>23 strike you as problematic that orders are</p> <p>24 being shipped prior to the due diligence</p> <p>25 being completed?</p>	<p style="text-align: center;">Page 125</p> <p>1 authenticity?</p> <p>2 A. No.</p> <p>3 Q. Okay. And here, Jim writes to</p> <p>4 Karen: As we discussed, I do not hold any</p> <p>5 orders while I do my research due to the time</p> <p>6 constraints.</p> <p>7 Are you aware of whether</p> <p>8 Mallinckrodt ever asked a company to return</p> <p>9 an order that had been shipped?</p> <p>10 A. Yes, I am aware we've asked</p> <p>11 customers to return orders that have been</p> <p>12 shipped.</p> <p>13 Q. Okay. And when you left</p> <p>14 Mallinckrodt, was it still Mallinckrodt's</p> <p>15 practice to ship, then investigate or</p> <p>16 complete the investigation of orders?</p> <p>17 MR. BERG: Object to form.</p> <p>18 A. I don't know.</p> <p>19 MS. KEECH: Okay. It's my</p> <p>20 understanding that the lunch is here.</p> <p>21 Do folks want to take a break now?</p> <p>22 MR. BERG: Sure.</p> <p>23 MS. KEECH: Or should we keep</p> <p>24 going?</p> <p>25 MR. BERG: Up to you. I don't</p>

Page 126	Page 128
<p>1 know how you're feeling.</p> <p>2 THE WITNESS: You want to maybe 3 go like 10 or 15 more minutes?</p> <p>4 MR. BERG: 12:30?</p> <p>5 MS. KEECH: Sure, that's fine.</p> <p>6 Okay, we'll go till 12:30.</p> <p>7 (Mallinckrodt-Saffold 8 Exhibit 18 was marked for 9 identification.)</p> <p>10 QUESTIONS BY MS. KEECH:</p> <p>11 Q. Okay. I'm handing you what has 12 been marked Exhibit 18, bearing Bates number 13 MNK-T1_0280678.</p> <p>14 Do you recognize this document?</p> <p>15 A. No.</p> <p>16 Q. Okay. What is it?</p> <p>17 A. It looks like either an e-mail 18 or a decline, you know, from a calendar 19 request from me to Karen on the 3rd of 20 November 2010, letting her know I won't be 21 able to make the meeting next week but I'm 22 comfortable with our progress and the 23 direction so far.</p> <p>24 Q. Okay. And what progress were 25 you referring to?</p>	<p>1 the SOM team?</p> <p>2 MR. BERG: Object to form.</p> <p>3 A. I said I can't really recall, 4 you know, like a specific decision.</p> <p>5 QUESTIONS BY MS. KEECH:</p> <p>6 Q. But generally speaking, did you 7 have access to the agendas and information of 8 the SOM team and projects that they were 9 working on?</p> <p>10 A. Yes.</p> <p>11 Q. Okay.</p> <p>12 (Mallinckrodt-Saffold 13 Exhibit 19 was marked for 14 identification.)</p> <p>15 QUESTIONS BY MS. KEECH:</p> <p>16 Q. I'm handing you what's been 17 marked as Exhibit 19, bearing Bates 18 MNK-T1_0000301254.</p> <p>19 A. Thank you.</p> <p>20 Q. Do you recognize this document?</p> <p>21 A. I think we saw something very 22 similar or this document earlier today.</p> <p>23 Q. Yes. We saw a very similar 24 document earlier today. If you'll turn with 25 me to the last page of this document where</p>
<p>1 A. I don't recall.</p> <p>2 Q. Do you recall what progress in 3 general the SOM team made from its inception 4 to November of 2010?</p> <p>5 A. No.</p> <p>6 Q. You noted that you were 7 "comfortable with our progress and direction 8 so far."</p> <p>9 Was there ever a time that you 10 were uncomfortable with the direction or 11 progress of the SOM team?</p> <p>12 A. No.</p> <p>13 Q. Were you ever uncomfortable 14 with decisions made regarding whether to 15 report an order or a circumstance to the DEA?</p> <p>16 A. No.</p> <p>17 Q. Did you ever disagree with 18 decisions that were made with respect to 19 Suspicious Order Monitoring?</p> <p>20 A. Not that I can recall, and I 21 don't think I was privy to a lot of decisions 22 being made.</p> <p>23 Q. So you were invited to the 24 meetings and invited to participate on the 25 algorithm but weren't privy to decisions of</p>	<p>127</p> <p>1 Cathy Stewart e-mails Karen Harper with a CC 2 to you on November 16th, 2009, she writes, 3 referencing the manual process, that it's a 4 process that lends itself to errors and 5 omissions.</p> <p>6 Are you aware of any shipments 7 that were sent to entities on the manual do 8 not ship list before it was transitioned to 9 SDIG -- or CDIG, excuse me?</p> <p>10 MR. BERG: Object to form.</p> <p>11 A. I'm not aware of any.</p> <p>12 QUESTIONS BY MS. KEECH:</p> <p>13 Q. Okay. So when she said it's a 14 process that lends itself to errors and 15 omissions, were you aware of any of those 16 errors or omissions that had occurred?</p> <p>17 A. No.</p> <p>18 Q. Okay. You can set that aside.</p> <p>19 (Mallinckrodt-Saffold 20 Exhibit 20 was marked for 21 identification.)</p> <p>22 QUESTIONS BY MS. KEECH:</p> <p>23 Q. I'm handing you what's been 24 marked as Exhibit 20, bearing Bates 25 MNK-T1_0000278389.</p>

Page 130	Page 132
<p>1 Are you familiar with this 2 document? 3 A. No. 4 Q. Any reason to doubt its 5 authenticity? 6 A. No. 7 Q. Okay. So at the bottom of this 8 e-mail thread, Karen Harper sends an e-mail 9 to Cathy Stewart and Jim Rausch with a copy 10 to you on November 6th, 2009, regarding the 11 Suspicious Order Monitoring program, work 12 instruction update, customer checklist 13 revisions and frequently asked question edit 14 changes.</p> <p>15 Jim then responds saying: We 16 removed the question "Does your company 17 verify that your customers have a Suspicious 18 Order Monitoring program as prescribed by 19 21 C.F.R. 1301.74" from the manufacturer's 20 questionnaire. Should it be removed from the 21 distributor and wholesaler questionnaires 22 also?</p> <p>23 Are you familiar with the 24 questionnaires that they're referencing? 25 A. I'm familiar that we had a</p>	<p>1 QUESTIONS BY MS. KEECH: 2 Q. Okay. Well, were you aware 3 that this question was removed from the 4 questionnaires? 5 A. I can't recall. 6 Q. Do you know why Mallinckrodt 7 would have removed that question? 8 A. I don't know. Aside from 9 compliance, right, I don't know much about 10 the questionnaire.</p> <p>11 Q. Okay. 12 (Mallinckrodt-Saffold 13 Exhibit 21 was marked for 14 identification.)</p> <p>15 QUESTIONS BY MS. KEECH: 16 Q. I'm handing you what's been 17 marked as Exhibit 21, bearing Bates number 18 MNK-T1_0004154291. This is an e-mail sent 19 from Cathy Stewart on November 6, 2009, to 20 you, Karen Harper and Jim Rausch.</p> <p>21 Karen then writes that she's 22 updated the bulk checklist to remove the 23 question relative to whether or not our 24 customer is verifying their customer has an 25 SOM program.</p>
<p>1 questionnaire. 2 Q. And what was the purpose of the 3 questionnaire, do you know? 4 A. Compliance, right. 5 Q. So Mallinckrodt would send 6 questionnaires to its distributors and 7 wholesalers, correct? 8 A. Yes. 9 Q. Okay. Did the questionnaires 10 assist in learning more about Mallinckrodt's 11 customers and whether they were aware of DEA 12 requirements? 13 A. I'm not really the author of 14 the questionnaire nor the driver of that 15 initiative, so I'm not comfortable commenting 16 on the questionnaire's purpose. 17 Q. Okay. Do you recall receiving 18 the e-mail reflecting updates to the SOM 19 procedures? 20 MR. BERG: Object to form. 21 A. No, I don't recall this. And 22 then, you know, I would point out that aside 23 from Karen's initial e-mail, I wasn't copied 24 on the subsequent e-mails so it's kind of 25 tough for me to even, you know, comment.</p>	<p>1 Page 133 2 MR. BERG: You know, Counsel, I 3 know you spent a lot of time with 4 these documents, but when you 5 introduce them, can you just point us 6 to where you're looking? 7 MS. KEECH: Sure. 8 MR. BERG: Because we haven't 9 had a chance to review them. 10 MS. KEECH: Sure. 11 MR. BERG: Thanks. 12 MS. KEECH: I'm also displaying 13 them here on the Elmo. I don't know 14 if you can see it. 15 MR. BERG: I can't see it. 16 Okay, I guess I can see some of it. 17 But just take your time, just 18 familiarize yourself with anything you 19 need to. 20 THE WITNESS: Okay, absolutely. 21 QUESTIONS BY MS. KEECH: 22 Q. So you were notified of this 23 decision to remove the question from the 24 questionnaire. Is that correct? 25 MR. BERG: Object to form. A. Yes.</p>

Page 134	Page 136
1 QUESTIONS BY MS. KEECH: 2 Q. Was this then or is it now 3 concerning to you that this question was 4 removed? 5 A. No. I don't know enough about 6 this to really be able to register a concern 7 about a question being removed. What makes 8 me have confidence is that we're very -- 9 we're working with our compliance person, so 10 I'm -- I wouldn't be concerned at all. "Bulk 11 checklist" would refer to API, so...	1 you may have had with counsel, did anyone 2 ever discuss with you whether Mallinckrodt 3 had an obligation to know its customer's 4 customer? 5 A. I don't recall any instances of 6 that, like a discussion on that, outside of 7 conversations with counsel. 8 Q. Okay. I'll rephrase the 9 question a little differently. So again, 10 outside of any conversation with counsel, did 11 you ever read any materials while you were at 12 Mallinckrodt or hear of this concept in any 13 form? 14 A. I don't recall. 15 Q. Okay. Thank you. 16 (Mallinckrodt-Saffold 17 Exhibit 22 was marked for 18 identification.)
15 MR. BERG: Object to form. 16 A. No, that's not really my area. 17 QUESTIONS BY MS. KEECH: 18 Q. Did anyone ever discuss whether 19 Mallinckrodt had an obligation to know its 20 customer's customer with you? 21 A. I think you may be asking me 22 about privileged information. Can I have 23 a -- so -- 24 MR. BERG: Well, before you 25 answer, like if you're concerned about	19 QUESTIONS BY MS. KEECH: 20 Q. I'm handing you what has been 21 marked Exhibit 22, bearing Bates number 22 MNK-T1_0000455782. 23 Do you recognize this document? 24 A. Yes. It's similar to a 25 document you showed me earlier.
1 Page 135 2 it, let's just step outside in the 3 hall and talk about it. 4 THE WITNESS: Yes, let's. 5 MR. BERG: Is that okay? 6 MS. KEECH: Sure. Do you want 7 to -- 8 MR. GOTTO: You want to take a 9 lunch break now? 10 MR. BERG: Okay. Sure. 11 MS. KEECH: Yeah. 12 THE VIDEOGRAPHER: All right. 13 Off the record at 12:18. 14 (Recess taken, 12:18? p.m. to 15 1:07? p.m.) 16 THE VIDEOGRAPHER: All right, 17 stand by. The time is 1:07, back on 18 the record. 19 QUESTIONS BY MS. KEECH: 20 Q. Thank you. 21 So before we broke earlier, I 22 asked you a question and you were going to 23 consult with your attorney, so I will 24 rephrase the question and you can answer it 25 again. 26 So apart from any conversations	1 Page 137 2 Q. Okay. And what is it? 3 A. It's a meeting request. 4 Q. Is it from Karen Harper, dated 5 July 22nd, 2010? 6 A. Yes. 7 Q. And are you on the recipient 8 list? 9 A. Yes. 10 Q. Okay. And does it state a 11 meeting purpose? 12 A. It does. 13 Q. And can you please read that 14 meeting purpose? 15 A. "Recent DEA enforcement action 16 taken within industry (including two 17 Mallinckrodt customers) merits a review of 18 our existing Controlled Substance Suspicious 19 Order Monitoring Program." 20 Q. So this indicates that two of 21 Mallinckrodt's customers got into trouble 22 with the DEA. Is that correct? 23 MR. BERG: Object to form. 24 A. It certainly -- I don't know. 25 Enforcement action, right, so I don't know if that's in trouble or...

Page 138	Page 140
<p>1 QUESTIONS BY MS. KEECH:</p> <p>2 Q. Sure.</p> <p>3 Does this represent that the</p> <p>4 DEA took enforcement action against two of</p> <p>5 Mallinckrodt's customers?</p> <p>6 A. It does.</p> <p>7 Q. Okay. And would you agree that</p> <p>8 because two of Mallinckrodt's customers had</p> <p>9 enforcement action taken against them that it</p> <p>10 was indicative that Mallinckrodt's Suspicious</p> <p>11 Order Monitoring program needed to be</p> <p>12 reviewed?</p> <p>13 MR. BERG: Objection to form.</p> <p>14 A. So I don't really have an</p> <p>15 opinion on that. I would defer to our</p> <p>16 compliance team.</p> <p>17 QUESTIONS BY MS. KEECH:</p> <p>18 Q. Okay. And earlier we discussed</p> <p>19 how Mallinckrodt chose to remove the question</p> <p>20 of whether its customers were verifying its</p> <p>21 customers had SOM programs in the</p> <p>22 questionnaire that it submitted.</p> <p>23 MR. BERG: Objection, form.</p> <p>24 A. So at the risk of being</p> <p>25 argumentative, I think that referred to a</p>	<p>1 aside from the monthly reports that they</p> <p>2 generated, what the nature of your</p> <p>3 supervision was? In other words, how often</p> <p>4 did you meet with them, did you have</p> <p>5 one-on-ones, how frequently did you</p> <p>6 communicate?</p> <p>7 MR. BERG: Object to form.</p> <p>8 A. Sure. It's -- I believe, you</p> <p>9 know, that we met, you know, I usually</p> <p>10 schedule weekly one-on-ones with my direct</p> <p>11 reports, so I think that would be consist --</p> <p>12 you know, I think that's what I had done.</p> <p>13 I don't specifically remember</p> <p>14 scheduling one-on-ones with them, but it's</p> <p>15 just that's what I do, and so -- and then</p> <p>16 also -- so that's, you know, aside from the</p> <p>17 monthly reports, that's, you know, how I got</p> <p>18 updates from them.</p> <p>19 QUESTIONS BY MS. KEECH:</p> <p>20 Q. And were the weekly meetings in</p> <p>21 person?</p> <p>22 A. Yes.</p> <p>23 Q. Do you recall about how long</p> <p>24 they lasted?</p> <p>25 A. I don't specifically recall any</p>
Page 139	Page 141
<p>1 bulk checklist and not necessarily a</p> <p>2 questionnaire that would be, you know, used</p> <p>3 for other types of customers.</p> <p>4 QUESTIONS BY MS. KEECH:</p> <p>5 Q. But you agree that that</p> <p>6 question was removed from the bulk checklist?</p> <p>7 MR. BERG: Object to form.</p> <p>8 A. It appears so. I'm not</p> <p>9 disputing that.</p> <p>10 QUESTIONS BY MS. KEECH:</p> <p>11 Q. Okay. And do you think that</p> <p>12 knowing the answer to that question would</p> <p>13 have been helpful in assessing whether</p> <p>14 Mallinckrodt should continue shipping product</p> <p>15 to its customers?</p> <p>16 A. I don't know.</p> <p>17 MR. BERG: Object to form.</p> <p>18 QUESTIONS BY MS. KEECH:</p> <p>19 Q. Okay. So I want to go back and</p> <p>20 talk with you about your supervision of your</p> <p>21 direct reports. You indicated earlier that</p> <p>22 you supervised both Jim Rausch and Cathy</p> <p>23 Stewart. Is that correct?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. Can you describe for me,</p>	<p>1 of the details of these meetings, so it would</p> <p>2 be tough to say.</p> <p>3 Q. Okay. Do you remember if it</p> <p>4 was a standing meeting or was it just more of</p> <p>5 an infrequent pop in, check in, see if you</p> <p>6 have any updates kind of a thing?</p> <p>7 A. I really don't recall the</p> <p>8 meetings, so it's kind of tough to say. I</p> <p>9 tend to schedule standing meetings with my</p> <p>10 direct reports.</p> <p>11 Q. Do you ever recall discussing</p> <p>12 with Jim Rausch the volume of peculiar orders</p> <p>13 that he was receiving?</p> <p>14 A. No.</p> <p>15 Q. Do you ever remember him saying</p> <p>16 that he was expending a large portion of his</p> <p>17 day reviewing peculiar orders?</p> <p>18 A. No.</p> <p>19 Q. Okay. And it's your</p> <p>20 understanding that there were changes to the</p> <p>21 Suspicious Order Monitoring program over</p> <p>22 time. Is that correct?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. And do you recall if any</p> <p>25 of those changes were based on the algorithm</p>

<p style="text-align: right;">Page 142</p> <p>1 used to flag whether an order was peculiar? 2 A. I don't know a lot of the 3 details on the changes, so I'm not sure I can 4 answer that question. 5 Q. Okay. Did you know whether one 6 of the factors evaluated was the historical 7 ordering patterns of a customer? 8 A. Yes. But just kind of at that 9 level, yes, historical order patterns are 10 something that is evaluated. 11 Q. And do you recall or know 12 whether the historical averages, as part of 13 the Suspicious Order Monitoring formula, ever 14 changed? 15 MR. BERG: Object to form. 16 A. I don't recall it necessarily 17 even being averages, so I don't really recall 18 what changes would have been made to it. 19 QUESTIONS BY MS. KEECH: 20 Q. Okay. Is the term "historical 21 average threshold" familiar to you? 22 A. I don't recall hearing it. 23 Q. Okay. I'm handing you what has 24 been marked as Exhibit 23. 25 (Mallinckrodt-Saffold</p>	<p style="text-align: right;">Page 144</p> <p>1 Q. What is 852 data? 2 A. So as I remember, EDI 852 data 3 is the information from like a wholesaler or 4 a distributor. 852 refers to an EDI 5 transaction. This transaction shows their 6 inventory and kind of their net -- and it can 7 show everything. It's always an inventory 8 transaction. 9 Q. Okay. 10 A. And then depending on what 11 other fields the distributor would send, it 12 may show other things as well. 13 Q. Okay. And what's the 14 significance of 852 data, if any? 15 A. So what that can show is if a 16 distributor, such as McKesson in this case, 17 says, hey, you're doing a bad job because 18 your orders aren't shipping out on time and 19 sometimes you don't have product. We say, 20 well, give us your 852 information, and we 21 can say, look, you're not having -- you know, 22 you have inventory on hand, so, yeah, we're 23 not filling your orders, but look, you're 24 still able to service your customers. 25 Q. Is 852 data something that you</p>
<p style="text-align: right;">Page 143</p> <p>1 Exhibit 23 was marked for 2 identification.) 3 QUESTIONS BY MS. KEECH: 4 Q. Bearing Bates number 5 MNK-T1_0005708609. 6 Do you recognize this document? 7 A. No. 8 Q. It's an e-mail from Debbie 9 Digby dated May 30th, 2012, addressed to you, 10 subject: Distributor EDI 852 - fill rate 11 information for McKesson. 12 A. Yes. 13 Q. Do you have any reason to doubt 14 the authenticity of this e-mail? 15 A. No. 16 Q. And do you recall who Debbie 17 Digby -- Digby, excuse me, is or what her 18 role at Mallinckrodt was? 19 A. No. No, sorry. 20 Q. Okay. And it indicates here 21 that you made a request for data. 22 A. Yes. 23 Q. Okay. And it appears that 24 Debbie provided EDI 852 data. 25 A. Yes.</p>	<p style="text-align: right;">Page 145</p> <p>1 regularly reviewed? 2 A. No. 3 Q. Do you recall why you wanted to 4 review it in this instance? 5 A. No. I think the speculation is 6 kind of in the answer I gave of probably 7 wanting to say we're maybe not as bad as 8 you're saying we are, but I don't know for 9 sure. 10 Q. Okay. And are you familiar 11 with 867 data? 12 A. No. Like I cannot tell you 13 what it is. 14 Q. Okay. Do you know whether 15 Mallinckrodt reviewed 867 data? 16 A. I don't know what 867 data is. 17 Q. Okay. How about 844 data? 18 A. I don't know. I don't remember 19 what that is either. 20 Q. Do you recall any other data 21 sources that you reviewed in your job? 22 MR. BERG: Object to form. 23 A. Are you talking about EDI data? 24 QUESTIONS BY MS. KEECH: 25 Q. Yeah.</p>

Page 146	Page 148
<p>1 A. Well, an 850, which is a 2 purchase order. I didn't really review the 3 data, but I remember, you know, because we'd 4 process orders, so that was a good one to 5 get. And then that's -- and then 856, which 6 is kind of an -- I think it's an order 7 acknowledgment, those were sometimes 8 distributors would want to make sure we were 9 sending them 856s. I think that's what an 10 856 is, but I'm not...</p> <p>11 Q. Okay. Thank you.</p> <p>12 Are you familiar with the term 13 "chargebacks"?</p> <p>14 A. Yes.</p> <p>15 Q. And what do you understand 16 chargebacks to be?</p> <p>17 A. It's pretty limited. So I 18 understand a chargeback refers to a 19 transaction generated from the distributor to 20 us or to, you know, the seller.</p> <p>21 Q. And is it your understanding 22 that the chargeback is the difference between 23 the list price and the contract price that 24 reconciles the two prices to make the 25 distributor whole?</p>	<p>1 October 27, 2011. Do you have any reason to 2 doubt its authenticity or that it was sent to 3 you?</p> <p>4 A. No.</p> <p>5 Q. Okay. And are you familiar 6 with the concept of future-dating?</p> <p>7 A. Yes.</p> <p>8 Q. What is future-dating?</p> <p>9 A. So future-dating is changing 10 the requested date on an order to a date in 11 the future. So, you know, an order has 12 several fields, date fields. So this is a 13 field where if you say, hey, I don't think 14 I'm going to be able to get you some product, 15 and so I can cancel the order or, you know, 16 if you want to wait a while for it, you know, 17 I can move this out 30, 45, 50 days, and then 18 you could change the future date, so you 19 still knew, hey, we are expected to fill this 20 order on this date now.</p> <p>21 Q. So when an order was 22 future-dated, when was the product actually 23 shipped?</p> <p>24 A. It would depend on -- you know, 25 typically it would be on the date that we</p>
Page 147	Page 149
<p>1 A. Yes.</p> <p>2 Q. Okay. And in your capacity as 3 director of customer service, did you review 4 chargeback data?</p> <p>5 A. No.</p> <p>6 Q. Did you have access to it?</p> <p>7 A. No.</p> <p>8 Q. Did you understand how the 9 company utilized it?</p> <p>10 A. No.</p> <p>11 Q. Okay.</p> <p>12 (Mallinckrodt-Saffold 13 Exhibit 24 was marked for 14 identification.)</p> <p>15 QUESTIONS BY MS. KEECH:</p> <p>16 Q. I'm handing you what's been 17 marked as Exhibit 24, bearing Bates number 18 MNK-T1_0000299450.</p> <p>19 (Document review by witness.)</p> <p>20 QUESTIONS BY MS. KEECH:</p> <p>21 Q. Okay. Do you recognize this 22 exhibit?</p> <p>23 A. Not really.</p> <p>24 Q. It's an e-mail from Lisa 25 Cardetti to you and Jim Rausch dated</p>	<p>1 changed the future date to, if that makes 2 sense.</p> <p>3 Q. If you received product before 4 the date in which the order was future-dated, 5 would it ship before that future date?</p> <p>6 A. I don't believe so.</p> <p>7 Q. Okay. And this e-mail 8 discusses a significant increase in oxycodone 9 15- and 30-milligram backorders. It appears 10 that manufacturing requested that the orders 11 be future-dated so that customers who already 12 received their allotted monthly quantity -- 13 quantity.</p> <p>14 You indicated on the first page 15 of the document, middle of the page, in the 16 e-mail from George Saffold to Lisa Cardetti, 17 October 27, 2011, that you would change the 18 notes on the order to state "Future dated Due 19 Excess Demand per Marketing. Customer has 20 already received their monthly allocation for 21 October 2011."</p> <p>22 When you wrote this note, where 23 was it actually recorded?</p> <p>24 MR. BERG: Object to form.</p> <p>25 A. So I didn't write this note on</p>

Page 150	Page 152
1 anything. 2 QUESTIONS BY MS. KEECH: 3 Q. Okay. 4 A. My team members who go in and 5 would change the dates, they would write that 6 note on the order header detail page in the 7 system of the order management system. 8 Q. So fair to say it was an 9 internal record? 10 A. Yes. 11 Q. Was this ever actually written 12 on a 222 form? 13 A. Not to my knowledge. 14 Q. So you provided the rationale 15 to your team members for what to write in 16 this instance. Is that correct? 17 MR. BERG: Object to form. 18 A. It provided the verbiage that 19 they were required to put on the order if 20 they were changing an order per this, you 21 know, kind of initiative. 22 QUESTIONS BY MS. KEECH: 23 Q. Okay. And the reason stated 24 was increased demand. 25 A. No.	1 A. Yes. 2 Q. And it lists AmerisourceBergen? 3 A. Yes. 4 Q. And also lists Cardinal Health? 5 A. Yes. 6 Q. Okay. Do you recall the 7 presentation we discussed earlier, 8 Exhibit 10? 9 A. Do you mind if I look? 10 Q. Sure. Yeah. 11 A. Yes. 12 Q. And this e-mail thread that's 13 in front of you is dated October 2011, 14 correct? 15 A. Yes, it is. 16 Q. Okay. And Exhibit 10 is dated 17 March of 2011. 18 A. Yes. 19 Q. And in Exhibit 10, page 9 of 20 Exhibit 10 lists distributors who the DEA had 21 taken enforcement action against, correct? 22 A. Yes. 23 Q. And it discusses license 24 suspension of AmerisourceBergen and Cardinal, 25 correct?
1 Q. Or excess demand. Is that 2 correct? 3 A. Excess demand, yes. 4 Q. Excess demand. 5 Are you aware of whether anyone 6 looked into the reason for the demand? 7 A. No. 8 Q. So do you know whether anyone 9 ever looked into whether the demand exceeded 10 the supply because the orders were 11 suspicious? 12 A. I wouldn't be aware of that. 13 Q. Okay. And on the third page of 14 this document, it indicates Lisa Cardetti 15 sent an e-mail on October 26, 2011, to Robert 16 Laznak. 17 Do you know who Robert Laznak 18 was? 19 A. I'm -- oh. No. 20 Q. In this e-mail to Robert or 21 Bob, Lisa indicates that the following 22 customers would have orders that would be 23 future-dated to November 1st for their 24 monthly allocation. 25 Do you see that?	1 A. Yes. 2 Q. Okay. So at the time that 3 Mallinckrodt future-dated the orders for 4 these entities, Mallinckrodt was aware of 5 their prior DEA enforcement actions. 6 MR. BERG: Object to form. 7 A. Apparently, yes. 8 QUESTIONS BY MS. KEECH: 9 Q. Was that then or is that now 10 concerning to you? 11 MR. BERG: Object to form. 12 A. No. 13 (Mallinckrodt-Saffold 14 Exhibit 25 was marked for 15 identification.) 16 QUESTIONS BY MS. KEECH: 17 Q. I'm handing you what's been 18 marked as Exhibit 25, bearing Bates number 19 MNK-T1_0005711355. This is an e-mail from 20 Carla Johnson dated October 26, 2011, to you 21 with a CC to Michael Santowski regarding 22 oxycodone orders. 23 Do you recognize this document? 24 A. No. 25 Q. Any reason to doubt its
Page 151	Page 153

Page 154	Page 156
1 authenticity? 2 A. No. 3 Q. Okay. So about in the middle 4 of the document, you sent an e-mail to Carla 5 Johnson, and who is Carla Johnson? 6 A. At the time, she was director 7 of planning. 8 Q. And in this, you -- actually, 9 can you read what you wrote to Carla? 10 A. "Hi, Carla. I just want to 11 make sure you are aware of this because I'm 12 not sure the direction on dating from Lisa is 13 consistent with our order management 14 policies. Did they run" -- do you want me to 15 read that? 16 Q. Yep. 17 A. "Did they run any of this by 18 you, because it seems like the changes you 19 made to the backorder report should address 20 manufacturing's concerns about the orders 21 showing up on backorder." 22 Q. And who is Michael Santowski? 23 A. The VP of supply chain. 24 Q. And Carla stated: Oxycodone 25 30s are the exception to the new backorder	1 you recall which management policy or 2 policies you were referring to? 3 A. I do. 4 Q. Okay. 5 A. So all of us in supply chain, 6 you know, we're -- a big metric for us is 7 service level, how many orders we can fill, 8 and that's not -- it's usually based on 9 demand. So if we're changing the requested 10 delivery date, it -- but if they had really 11 wanted it earlier, it might kind of look like 12 we were changing the numbers to get like a 13 better fill rate. So I wanted to make sure 14 that everyone was comfortable with doing that 15 and we were making sure that we -- you know, 16 that everyone was aware of it. 17 Q. So other than sending this 18 e-mail to Carla Johnson, do you recall 19 whether you raised this issue with anyone 20 else? 21 A. Yes. 22 Q. And did you? 23 A. Yes. I raised this issue to 24 Mike Santowski, and again, for the reason of, 25 like, hey, umm, I'm changing an order or my
Page 155	Page 157
1 report logic because we are not storing that 2 inventory in a shippable branch plant. 3 A. Yes. 4 Q. Do you know why oxy 30s would 5 be an exception? 6 MR. BERG: Object to form. 7 A. No, other than that they are 8 not storing the inventory -- I mean, other 9 than what's stated there, no. 10 QUESTIONS BY MS. KEECH: 11 Q. Okay. And then can you read 12 what Carla wrote next, beginning with "This 13 is"?: 14 A. "This is going to be an ongoing 15 issue; so I think it makes sense to take a 16 different approach. So I would say I'm in 17 alignment." 18 Q. So fair to say Carla approved 19 the proposed future-dating practice? 20 MR. BERG: Object to form. 21 A. I think that's fair. 22 QUESTIONS BY MS. KEECH: 23 Q. So when you said you weren't 24 sure that the direction on dating from Lisa 25 was consistent with management policies, do	1 people are changing a requested date. You 2 know, do you think this is okay in this 3 situation? 4 Q. And what response, if any, did 5 you get? 6 A. A good response. He said -- 7 you know, he said yes, and then he confirmed 8 that, you know, for us to change the order, 9 there had to be a conversation with a 10 customer led by, you know, the commercial 11 organization saying, you know, hey, are you 12 okay with us changing the date, here's why 13 we're changing the date. So it wasn't just 14 like we were wholesale looking at orders that 15 were backordered, that there was actually 16 some discipline applied to this. 17 Q. So when that conversation 18 occurred with the customer, was that in 19 writing, over the phone? 20 A. I'm not sure. 21 Q. Okay. Do you know who had that 22 conversation? 23 A. I don't recall. 24 Q. Okay. Did you raise it with 25 anyone else other than Mike Santowski and

Page 158	Page 160
<p>1 Carla Johnson?</p> <p>2 A. No.</p> <p>3 Q. Okay. Were you satisfied with</p> <p>4 the answer that Mike Santowski gave you?</p> <p>5 A. Yes. In terms of raising it to</p> <p>6 other people -- let me rephrase that. I</p> <p>7 don't remember whether I did or not, but I do</p> <p>8 remember being satisfied with the answer.</p> <p>9 Q. Okay. So what was the benefit</p> <p>10 to Mallinckrodt of future-dating an order?</p> <p>11 MR. BERG: Object to form.</p> <p>12 A. I'm not 100% sure.</p> <p>13 QUESTIONS BY MS. KEECH:</p> <p>14 Q. Do you have an idea as to how</p> <p>15 it benefited Mallinckrodt in any way?</p> <p>16 A. So, yeah. I think it made</p> <p>17 it -- it made our order management system,</p> <p>18 which gives requirements to manufacturing and</p> <p>19 helps us plan our activities, match more of</p> <p>20 what we were actually doing.</p> <p>21 And then also, it made our --</p> <p>22 once all the dates matched, then you can do</p> <p>23 things like make sure you're planning the</p> <p>24 right transportation, so it just made</p> <p>25 everything more accurate.</p>	<p>1 you're not sure whether a customer's ordering</p> <p>2 history was significant when evaluating its</p> <p>3 orders?</p> <p>4 MR. BERG: Object to form.</p> <p>5 A. So I believe it was, you know,</p> <p>6 but I don't know specifically what elements</p> <p>7 of order history were, you know, used.</p> <p>8 QUESTIONS BY MS. KEECH:</p> <p>9 Q. Okay. So it's fair to say that</p> <p>10 future-dating allowed Mallinckrodt to sell</p> <p>11 opioids to a wholesale distributor customer</p> <p>12 without triggering some kind of suspicious</p> <p>13 order review?</p> <p>14 MR. BERG: Object to form.</p> <p>15 A. I would say that is not fair to</p> <p>16 say.</p> <p>17 QUESTIONS BY MS. KEECH:</p> <p>18 Q. So do you know whether, when</p> <p>19 orders were future-dated, an evaluation</p> <p>20 occurred of that distributor for whether its</p> <p>21 orders were suspicious --</p> <p>22 MR. BERG: Object --</p> <p>23 QUESTIONS BY MS. KEECH:</p> <p>24 Q. -- prior to the future-dating?</p> <p>25 MR. BERG: Object to form.</p>
<p style="text-align: center;">Page 159</p> <p>1 Q. Okay. And to your knowledge,</p> <p>2 was the Suspicious Order Monitoring algorithm</p> <p>3 based in part on order history of customers?</p> <p>4 MR. BERG: Object to form.</p> <p>5 A. With very limited knowledge of</p> <p>6 the actual algorithm, I understand that was</p> <p>7 one of its features.</p> <p>8 QUESTIONS BY MS. KEECH:</p> <p>9 Q. Okay. So fair to say the order</p> <p>10 history in any given month was a relevant</p> <p>11 factor in analysis of whether a customer had</p> <p>12 suspicious orders?</p> <p>13 MR. BERG: Object to form.</p> <p>14 A. Can you repeat that? I don't</p> <p>15 know if I understood the question.</p> <p>16 QUESTIONS BY MS. KEECH:</p> <p>17 Q. Sure.</p> <p>18 Did a customer's order history</p> <p>19 in any given month, was that relevant in the</p> <p>20 analysis of whether a customer had a</p> <p>21 suspicious order?</p> <p>22 A. Again, without knowing the --</p> <p>23 you know, the algorithm rules, it would be</p> <p>24 hard to say.</p> <p>25 Q. So just generally speaking,</p>	<p style="text-align: center;">Page 161</p> <p>1 A. My understanding of the</p> <p>2 Suspicious Order Management program and how</p> <p>3 it interacted with the order management</p> <p>4 system was that every order was reviewed.</p> <p>5 QUESTIONS BY MS. KEECH:</p> <p>6 Q. Okay. If an order was</p> <p>7 future-dated, the sales to that particular</p> <p>8 wholesale distributor would not exceed the</p> <p>9 threshold for review set by the Suspicious</p> <p>10 Order Monitoring algorithm for the time</p> <p>11 period in which the sale in fact occurred.</p> <p>12 Is that correct?</p> <p>13 MR. BERG: Objection. Object</p> <p>14 to form.</p> <p>15 A. I'm not sure. There were</p> <p>16 several dates on an order, one of them being</p> <p>17 order date, which is immutable, or at least I</p> <p>18 don't think you could move it, and we never</p> <p>19 did. And the other was requested date, which</p> <p>20 referred to requested delivery date.</p> <p>21 So I'm not sure how the -- what</p> <p>22 date Suspicious Order Monitoring looked at,</p> <p>23 but we made sure we maintained the integrity</p> <p>24 of the order by not altering that order date</p> <p>25 and only the requested delivery date because</p>

Page 162	Page 164
<p>1 we had a conversation with the customer 2 saying, hey, I can't get it to you this date, 3 can you have it later. They said yes, then 4 we said, okay, we're changing your date to 5 here.</p> <p>6 So I'm not sure how that 7 interacts with Suspicious Order Monitoring.</p> <p>8 QUESTIONS BY MS. KEECH:</p> <p>9 Q. Okay. Do you know whether 222 10 forms have an expiration date on them?</p> <p>11 A. I do know they do.</p> <p>12 Q. Okay.</p> <p>13 (Mallinckrodt-Saffold 14 Exhibit 26 was marked for 15 identification.)</p> <p>16 QUESTIONS BY MS. KEECH:</p> <p>17 Q. I'm handing you what has been 18 marked Exhibit 26, bearing Bates number 19 MNK-T1_0002742739.</p> <p>20 A. Thank you.</p> <p>21 Q. This is an e-mail sent from Jim 22 Rausch on October 27, 2011, and you were 23 included on the CC field, subject line: 24 Oxycodone orders.</p> <p>25 Do you recognize this document?</p>	<p>1 Q. Do you see anything wrong with 2 that practice?</p> <p>3 MR. BERG: Object to form.</p> <p>4 A. No. (Mallinckrodt-Saffold 5 Exhibit 27 was marked for 6 identification.)</p> <p>8 QUESTIONS BY MS. KEECH:</p> <p>9 Q. Okay. I'm handing you what's 10 been marked Exhibit 27, bearing Bates number 11 MNK-T1_000299509.</p> <p>12 Do you remember this document?</p> <p>13 A. No.</p> <p>14 Q. Okay. Any reason to doubt its 15 authenticity?</p> <p>16 A. No.</p> <p>17 Q. Okay. And this is an e-mail 18 sent from Lisa Cardetti to Ginger Collier 19 with a CC to both you and Jim Rausch sent 20 October 4th, 2011. The subject line: Pharma 21 Backorder Report - Summary.</p> <p>22 And Lisa writes: In working 23 with customer service, we've eliminated the 24 backorders on oxycodone IR by future-dating 25 orders. I wanted to make you aware that this</p>
<p>1 A. I need a moment. (Document review by witness.)</p> <p>3 A. It looks very similar to the 4 prior -- an e-mail you showed me prior, maybe 5 with just some more comments on it, so yes.</p> <p>6 QUESTIONS BY MS. KEECH:</p> <p>7 Q. Okay. And on the first page of 8 this document, Sharron Banks sent an e-mail 9 on October 27th, 2011, to Jim Rausch and a 10 number of others with a CC to you and stated: 11 Jim, there's a possibility that the 222 forms 12 may expire by the desired requested date.</p> <p>13 And then can you read Jim's 14 response at the top of the document?</p> <p>15 A. Sure.</p> <p>16 "We'll see how many orders we 17 have that won't allow us to future date it to 18 new date because of the 222 form expiration 19 date. If that happens we will need -- would 20 need to ask the customer to send us a new 21 form with the reason that we won't have any 22 more oxycodone for them until the future date 23 and reenter the order with the new 222 form. 24 We'll discuss it more if and when it comes 25 up."</p>	<p>1 initiative/process will continue through 2 January.</p> <p>3 So based on your recollection 4 and review of these documents, is it fair to 5 say that the future-dating process began in 6 October of 2011?</p> <p>7 A. Yes.</p> <p>8 Q. Are you aware of whether 9 Mallinckrodt future-dated any orders prior to 10 2011?</p> <p>11 A. No.</p> <p>12 Q. Okay. And this indicates that 13 it continued through January 2012?</p> <p>14 A. Yes.</p> <p>15 Q. And are you aware of whether 16 Mallinckrodt continued to future-date any 17 orders after January of 2012?</p> <p>18 A. I don't recall.</p> <p>19 Q. Okay. Is future-dating 20 authorized by the DEA?</p> <p>21 MR. BERG: Object to form.</p> <p>22 A. I don't know.</p> <p>23 QUESTIONS BY MS. KEECH:</p> <p>24 Q. Do you know who Pat Wall is?</p> <p>25 A. Yes.</p>

Page 166	Page 168
<p>1 Q. Who is Pat Wall?</p> <p>2 A. Pat Wall is a customer service</p> <p>3 agent. She worked as -- in respiratory</p> <p>4 customer service and then respiratory</p> <p>5 customer service as a supervisor and then</p> <p>6 went over to dosage customer service as kind</p> <p>7 of an agent.</p> <p>8 (Mallinckrodt-Saffold</p> <p>9 Exhibit 28 was marked for</p> <p>10 identification.)</p> <p>11 QUESTIONS BY MS. KEECH:</p> <p>12 Q. Okay. I'm handing you a</p> <p>13 document labeled Exhibit 28, bearing Bates</p> <p>14 number MNK-T1_0004595958.</p> <p>15 (Document review by witness.)</p> <p>16 QUESTIONS BY MS. KEECH:</p> <p>17 Q. Do you recognize this document?</p> <p>18 A. Yes.</p> <p>19 Q. What is it?</p> <p>20 A. It is an FAQ for the purpose of</p> <p>21 loading it into a knowledge management system</p> <p>22 I was trying to launch.</p> <p>23 Q. So did you have a role in</p> <p>24 generating this document?</p> <p>25 A. No.</p>	<p>1 of the product, so --</p> <p>2 Q. So let me clarify it. Would it</p> <p>3 be a violation of DEA regulations to ship a</p> <p>4 Schedule II narcotic without a 222 form?</p> <p>5 MR. BERG: Object to form.</p> <p>6 A. I believe so, yes.</p> <p>7 QUESTIONS BY MS. KEECH:</p> <p>8 Q. Thank you.</p> <p>9 A. Oh, and keep in mind also,</p> <p>10 CSOS, right, so all Schedule II orders do not</p> <p>11 require a 222 form; only those that are</p> <p>12 manual, right. If a distributor or</p> <p>13 wholesaler orders electronically using the</p> <p>14 Controlled Substance Ordering System, that</p> <p>15 kind of 222 compliance activity is handled</p> <p>16 electronically. Then an order would not have</p> <p>17 that.</p> <p>18 Q. Thanks for clarifying.</p> <p>19 A. Sorry.</p> <p>20 Q. That's okay.</p> <p>21 THE WITNESS: Is this a good</p> <p>22 time to break, maybe, and see if the</p> <p>23 coffee is here?</p> <p>24 MS. KEECH: Yes, we can do</p> <p>25 that. That's a good idea.</p>
<p>1 Q. Okay. But you're familiar with</p> <p>2 it?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. And can you read the</p> <p>5 fifth sentence on the first page, beginning</p> <p>6 with "Can 222 forms be post or future dated"?</p> <p>7 A. "Can 222 forms be post or</p> <p>8 future dated? No, 222 forms are dated on the</p> <p>9 actual date they are completed."</p> <p>10 Q. And what about the</p> <p>11 second-to-last question on page 1, beginning</p> <p>12 "What if I make a mistake while completing</p> <p>13 the 222 form?"</p> <p>14 A. "What if I make a mistake while</p> <p>15 completing the 222 form? Can I correct it?</p> <p>16 No, there can be no corrections or markovers</p> <p>17 on a 222 form. You will need to complete and</p> <p>18 send in another 222 form that is completed</p> <p>19 correctly."</p> <p>20 Q. So fair to say it's important</p> <p>21 that the 222 forms are filled out correctly?</p> <p>22 A. Yes.</p> <p>23 Q. And is it okay to ship a</p> <p>24 product without a 222 form?</p> <p>25 A. If -- depending on the schedule</p>	<p>1 Page 167</p> <p>1 THE VIDEOGRAPHER: Off the</p> <p>2 record at 1:52.</p> <p>3 (Recess taken, 1:52?p.m. to</p> <p>4 2:00?p.m.)</p> <p>5 THE VIDEOGRAPHER: All right,</p> <p>6 stand by. The time is 2:00 o'clock</p> <p>7 p.m. Back on the record, beginning of</p> <p>8 File 3.</p> <p>9 (Mallinckrodt-Saffold</p> <p>10 Exhibit 29 was marked for</p> <p>11 identification.)</p> <p>12 QUESTIONS BY MS. KEECH:</p> <p>13 Q. Okay. I'm handing you what's</p> <p>14 been marked as Exhibit 29, bearing Bates</p> <p>15 number MNK-T1_0000368976.</p> <p>16 Do you recognize this document?</p> <p>17 A. No.</p> <p>18 Q. Any reason to doubt its</p> <p>19 authenticity?</p> <p>20 A. No.</p> <p>21 Q. And this is a 2010 e-mail chain</p> <p>22 started by Cheryl Nelson regarding the state</p> <p>23 of Florida and oxycodone prices.</p> <p>24 Can you read aloud at the</p> <p>25 bottom of the first page?</p>

Page 170	Page 172
<p>1 A. "We have received numerous 2 calls this week from persons living in 3 Florida who are trying to have their oxy 4 30-milligram prescriptions filled. They are 5 complaining that the pharmacies are 6 price-gouging by charging 5 and 6 dollars per 7 pill versus 1.50 the last time they had their 8 prescriptions filled, if the pharmacy has the 9 product at all. When a person will give me 10 their name and phone number, I take it, but 11 some just won't give that information."</p> <p>12 Q. And you were CC'd on that 13 e-mail?</p> <p>14 A. Yes.</p> <p>15 Q. Okay.</p> <p>16 A. Yes.</p> <p>17 Q. Okay. So fair to say that you 18 were notified about customer service 19 complaints indicating that pharmacies in 20 Florida were increasing their oxy prices and 21 price-gouging by 5 to 6 dollars a pill?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And you responded to 24 this e-mail to Mike Gunning and Ginger 25 Collier. And who is Mike Gunning?</p>	<p>1 situation.</p> <p>2 Q. Okay. When you said "We are 3 sticking with our messaging," do you recall 4 who determined the content of this message?</p> <p>5 A. I really don't remember this, 6 this instance.</p> <p>7 Q. Okay. Ginger writes at the top 8 of the e-mail, "I am assuming these are cash 9 customers."</p> <p>10 What's the significance, if 11 anything, of customers paying in cash?</p> <p>12 MR. BERG: Object to form.</p> <p>13 A. I don't know.</p> <p>14 QUESTIONS BY MS. KEECH:</p> <p>15 Q. Have you ever heard anyone 16 indicate that paying in cash for opioids is a 17 possible indicator of diversion?</p> <p>18 A. No.</p> <p>19 Q. Do you know whether 20 Mallinckrodt determines whether the customers 21 were independent or retail pharmacies?</p> <p>22 MR. BERG: Object to form.</p> <p>23 A. I'm sorry, what was the 24 question?</p> <p>25 QUESTIONS BY MS. KEECH:</p>
<p>1 A. I don't know his title. He's 2 kind of like the head guy in the controlled 3 substance -- or in the dosage group.</p> <p>4 Q. Okay. And can you please read 5 what you wrote to Mike and Ginger?</p> <p>6 A. "Just a note to let you know 7 that not only is the frequency of calls 8 regarding oxy availability in Florida picking 9 up but also the nature of the complaints are 10 changing from simple availability to 11 price-gouging and availability. We are 12 sticking with our message that we have not 13 interrupted our supply to wholesalers and 14 that these issues are the result of scrutiny 15 by the DEA in the state of Florida."</p> <p>16 Q. And how did you become aware of 17 the frequency of the call increases?</p> <p>18 A. I really don't remember.</p> <p>19 Q. Do you know when you would have 20 become aware of that?</p> <p>21 A. I really don't remember.</p> <p>22 Q. Okay. Was it at all concerning 23 to you when you learned of this situation in 24 Florida?</p> <p>25 A. I don't really remember the</p>	<p>1 Q. Do you know whether 2 Mallinckrodt determined whether the customers 3 were independent or retail pharmacies?</p> <p>4 MR. BERG: Object to form.</p> <p>5 A. I don't know.</p> <p>6 QUESTIONS BY MS. KEECH:</p> <p>7 Q. Okay. (Mallinckrodt-Saffold 8 Exhibit 30 was marked for 9 identification.)</p> <p>11 QUESTIONS BY MS. KEECH:</p> <p>12 Q. I'm handing you what's been 13 marked as Exhibit 30, bearing Bates number 14 MNK-T1_0000299364.</p> <p>15 A. Thank you. (Document review by witness.)</p> <p>17 QUESTIONS BY MS. KEECH:</p> <p>18 Q. Do you recognize this document?</p> <p>19 A. No.</p> <p>20 Q. Any reason to doubt its 21 authenticity?</p> <p>22 A. No.</p> <p>23 Q. Okay. This appears to be a 24 document sent from Cheryl Nelson to you and 25 Jim Rausch with a CC to Brenda Rehkop in</p>

Page 174	Page 176
<p>1 September of 2011.</p> <p>2 A. Yes.</p> <p>3 Q. And Jim e-mailed you, if you</p> <p>4 turn to page 2, checking to see if orders</p> <p>5 should still be cancelled. Is that correct?</p> <p>6 A. Yes.</p> <p>7 Q. Cheryl then says -- whoops --</p> <p>8 "I have cancelled this line and did not</p> <p>9 reenter it as it is my understanding that we</p> <p>10 are not shipping 15- or 30-milligram oxy to</p> <p>11 Florida."</p> <p>12 Do you know why there was a</p> <p>13 decision or concern not to ship oxy 15 or 30s</p> <p>14 to Florida?</p> <p>15 A. I don't remember.</p> <p>16 Q. Are you aware of whether oxy</p> <p>17 15s and 30s were pills that were commonly</p> <p>18 abused?</p> <p>19 A. Yes. I am aware, and I believe</p> <p>20 they were.</p> <p>21 Q. Are you aware of what</p> <p>22 precipitated the discussion or decision not</p> <p>23 to ship oxy 15s and 30s to Florida?</p> <p>24 A. No.</p> <p>25 Q. And do you know what decision</p>	<p>1 A. No.</p> <p>2 Q. Any reason to doubt its</p> <p>3 authenticity?</p> <p>4 A. No.</p> <p>5 Q. Okay. So in this document, you</p> <p>6 sent an e-mail to Michael Santowski regarding</p> <p>7 these orders that were accidentally shipped.</p> <p>8 The first page, third paragraph, can you read</p> <p>9 the sentence beginning with the word</p> <p>10 "Apparently"?</p> <p>11 A. "Apparently the product was</p> <p>12 pulled back from the orders and set to the</p> <p>13 side. It appears, however, the next shift</p> <p>14 came in and assumed they were left off these</p> <p>15 orders unintentionally and then shipped them</p> <p>16 out."</p> <p>17 Q. And then you provided a</p> <p>18 timeline for each of the orders?</p> <p>19 A. Yes.</p> <p>20 Q. And this shows that 84 bottles</p> <p>21 went to ABC in Orlando, Florida?</p> <p>22 A. Yes.</p> <p>23 Q. It also shows that 48 bottles</p> <p>24 of 30-milligram oxy went to Prescription</p> <p>25 Supply in Northwood, Ohio?</p>
Page 175	Page 177
<p>1 Mallinckrodt ultimately made with regard to</p> <p>2 shipping oxy 15s and 30s to Florida?</p> <p>3 A. I really don't remember this,</p> <p>4 so no.</p> <p>5 Q. Okay. So you don't remember</p> <p>6 writing, "While it's my expectation that we</p> <p>7 may not be shipping the 15s and 30s to</p> <p>8 Florida, I'm not sure how well that decision</p> <p>9 has been finalized and communicated"?</p> <p>10 MR. BERG: Object to form.</p> <p>11 A. Yeah. I don't remember this.</p> <p>12 (Mallinckrodt-Saffold</p> <p>13 Exhibit 31 was marked for</p> <p>14 identification.)</p> <p>15 QUESTIONS BY MS. KEECH:</p> <p>16 Q. I'm handing you Exhibit 31,</p> <p>17 bearing Bates number MNK-T1_0003064400.</p> <p>18 (Document review by witness.)</p> <p>19 QUESTIONS BY MS. KEECH:</p> <p>20 Q. So I've handed you an internal</p> <p>21 e-mail chain regarding a series of orders for</p> <p>22 oxycodone which were accidentally shipped.</p> <p>23 Do you recall this incident?</p> <p>24 A. No.</p> <p>25 Q. Do you recognize this document?</p>	<p>1 A. Yes.</p> <p>2 Q. And it also shows that an</p> <p>3 undisclosed amount was shipped to ABC in</p> <p>4 Sacramento, California?</p> <p>5 A. Yes.</p> <p>6 Q. So accidentally shipping orders</p> <p>7 is not an ideal scenario from a customer</p> <p>8 service aspect, correct?</p> <p>9 A. Correct.</p> <p>10 Q. It's actually pretty bad,</p> <p>11 right?</p> <p>12 MR. BERG: Object to form.</p> <p>13 A. Yeah. Yes.</p> <p>14 QUESTIONS BY MS. KEECH:</p> <p>15 Q. And you e-mailed Michael</p> <p>16 Santowski alerting him to this situation,</p> <p>17 correct?</p> <p>18 A. Yes.</p> <p>19 Q. And who is Michael Santowski?</p> <p>20 A. He's my direct supervisor.</p> <p>21 Q. Okay. How frequently do you</p> <p>22 recall communicating with him?</p> <p>23 A. Pretty frequently. He was my</p> <p>24 direct supervisor.</p> <p>25 Q. Okay. Would you agree that</p>

Page 178	Page 180
<p>1 shipping orders that were not supposed to be 2 shipped is an example of diversion? 3 MR. BERG: Object to form. 4 A. I don't know if it is. 5 QUESTIONS BY MS. KEECH: 6 Q. Is it an example of lack of 7 internal controls? 8 MR. BERG: Object to form. 9 A. No, it's not. 10 QUESTIONS BY MS. KEECH: 11 Q. Is this example an example of 12 lack of communication? 13 A. No. 14 Q. Do you know whether this event 15 was reported to the DEA? 16 A. I do not know. 17 Q. Do you know what, if anything, 18 happened after you sent this e-mail? 19 A. I don't remember. 20 Q. Okay. 21 (Mallinckrodt-Saffold 22 Exhibit 32 was marked for 23 identification.) 24 QUESTIONS BY MS. KEECH: 25 Q. I'm handing you what's been</p>	<p>1 conversation with those individuals regarding 2 customer registrant DEA license suspensions? 3 A. I don't recall, like, specific 4 conversations about this. 5 Q. Do you recall talking with 6 anyone about Mallinckrodt [sic] about the 7 license suspensions of either Harvard or 8 Sunrise? 9 A. I don't recall talking with 10 anybody about it. I recall that Harvard was 11 suspended. 12 Q. Okay. Maybe I'll expand that 13 question. Do you recall any communications 14 regarding the DEA license suspensions of 15 Harvard? 16 A. Not specifically, no. 17 Q. Even if you don't recall the 18 content of the communications, do you recall 19 whether there were any communications or any 20 reference at all to either the Harvard or 21 Sunrise? 22 A. Yes. 23 Q. Okay. And what do you recall? 24 A. I recall that we were notified 25 that Harvard was suspended.</p>
<p style="text-align: center;">Page 179</p> <p>1 marked as Exhibit 32, bearing Bates stamp 2 MNK-T1_0000279164. 3 (Document review by witness.) 4 QUESTIONS BY MS. KEECH: 5 Q. Okay? Do you recall receiving 6 this e-mail? 7 A. No. 8 Q. Any reason to doubt its 9 authenticity? 10 A. Well, I didn't ever receive 11 this e-mail. 12 Q. Correct. You were referenced 13 in this e-mail. Do you recall, thank you -- 14 this indicates this e-mail's sent from Karen 15 Harper to JoAnne Levy dated June 17th, 2010, 16 subject line: Conference Call with Customer 17 Service and Compliance - Harvard and Sunshine 18 DEA Registration Suspensions. 19 And Karen writes: JoAnne, 20 yesterday I set up a call for this morning 21 with me, George Saffold, Jim Rausch and 22 Eileen to discuss customer registrant DEA 23 license suspensions and Mallinckrodt 24 Suspicious Order Monitoring. 25 Do you recall ever having a</p>	<p style="text-align: center;">Page 181</p> <p>1 Q. Do you recall who notified you? 2 A. No. I -- no. I think it was 3 Karen, but I'm not 100% sure. 4 Q. Do you recall how you learned 5 about it? 6 A. No. 7 Q. Do you remember the content of 8 discussions after learning about DEA license 9 suspensions of Mallinckrodt customers? 10 A. No. 11 Q. Do you recall the action plan 12 that Mallinckrodt took after learning of DEA 13 license suspensions? 14 MR. BERG: Object to form. 15 A. I recall that we took some 16 actions and I recall some of the actions, but 17 I don't think I could tell you the whole 18 action plan. 19 QUESTIONS BY MS. KEECH: 20 Q. Okay. And in this e-mail, 21 Karen also writes, "I'm pretty confident we 22 can pull in the reins and keep the situation 23 under control," and this was dated June 24 of 2010. 25 A. Yes.</p>

Page 182	Page 184
<p>1 Q. Are you aware of whether any of 2 Mallinckrodt's customers had any enforcement 3 action after June of 2010?</p> <p>4 MR. BERG: Object to form.</p> <p>5 A. I don't recall.</p> <p>6 QUESTIONS BY MS. KEECH:</p> <p>7 Q. Okay.</p> <p>8 (Sotto voce discussion.)</p> <p>9 (Mallinckrodt-Saffold</p> <p>10 Exhibit 33 was marked for 11 identification.)</p> <p>12 QUESTIONS BY MS. KEECH:</p> <p>13 Q. Okay. I'm handing you what's 14 been marked as Exhibit 33 --</p> <p>15 A. Thank you.</p> <p>16 Q. -- bearing Bates 17 MNK-T1_0000495396. 18 (Document review by witness.)</p> <p>19 QUESTIONS BY MS. KEECH:</p> <p>20 Q. Okay. Are you familiar with 21 this document?</p> <p>22 A. No.</p> <p>23 Q. Any reason to doubt its 24 authenticity?</p> <p>25 A. No.</p>	<p>1 also indicates that Masters received the 2 fentanyl patch and morphine sulfate, which is 3 a Schedule II controlled substance, correct?</p> <p>4 A. So methylphenidate is a 5 nonnarcotic C-II. Is that your question?</p> <p>6 Q. Okay. But the fentanyl 7 patch --</p> <p>8 A. Is a C-II, I believe.</p> <p>9 Q. Okay. Thank you.</p> <p>10 Does reviewing this e-mail 11 thread refresh your recollection of what 12 happened?</p> <p>13 A. Yes.</p> <p>14 Q. And can you describe what 15 happened?</p> <p>16 A. So I can't speak to, you know, 17 every aspect of it. But in general terms, we 18 had some product ordered and we had, you 19 know, product restricted, and some of the 20 product that should have been restricted, it 21 was ordered. We detected that, and we were 22 able to get the product back and off the 23 market, and then, you know, made sure that we 24 were communicating that, hey, this happened, 25 let's make sure we don't do this again.</p>
<p>1 Q. Okay. And this is an e-mail 2 thread. The top of the e-mail thread, the 3 e-mail is from you to Brenda Rehkop, Jim 4 Rausch and Karen Harper dated July 13th, 5 2011, regarding Masters recent shipments - 6 G. Saffold recommendation for systems review.</p> <p>7 A. Yes.</p> <p>8 Q. And towards the bottom of the 9 e-mail thread on page 2, Karen Harper sends 10 an e-mail to Jane Williams indicating that 11 George Saffold advised this morning that 12 Masters has gotten two shipments since 13 Mallinckrodt imposed shipping restrictions on 14 this account within the scope of Suspicious 15 Order Monitoring.</p> <p>16 Do you recall this occurring?</p> <p>17 A. A little. Like kind of 18 vaguely, yes.</p> <p>19 Q. Right. Reading this 20 document --</p> <p>21 A. Yes.</p> <p>22 Q. -- refreshes your recollection 23 a little bit?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. And this e-mail thread</p>	<p>1 Q. Okay. And at the top of this 2 e-mail thread, you write an e-mail to Karen 3 Harper where you say: This reveals a clear 4 gap in our process. I think we should review 5 it cradle to grave to see where we can 6 improve it first to make sure that the time 7 from customer notification to restricting 8 shipments is more immediate, and second, to 9 ensure e --</p> <p>10 A. We, probably, right.</p> <p>11 Q. -- cannot ship out any product 12 once we have placed these restrictions on the 13 customer.</p> <p>14 A. Yes.</p> <p>15 Q. So you acknowledge that there 16 was a gap in the process at that time.</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And what, if anything, 19 do you recall that was done after you sent 20 this e-mail?</p> <p>21 A. I don't recall specifically 22 what was done. I do remember there was -- 23 you know, that cradle to grave did occur. I 24 don't think I was in that actual meeting 25 where they kind of mapped it out and felt</p>

Page 186	Page 188
<p>1 like they closed the gaps.</p> <p>2 Q. Okay. And in this document</p> <p>3 also appears that in July of 2011,</p> <p>4 Mallinckrodt was placing restrictions on five</p> <p>5 accounts, in the bottom of this first page on</p> <p>6 to the second page.</p> <p>7 A. Yes.</p> <p>8 Q. And what were those five</p> <p>9 accounts?</p> <p>10 A. I'm reading them from here:</p> <p>11 KeySource, Masters, Harvard, Cedardale, and</p> <p>12 Sunrise.</p> <p>13 Q. Okay. And were you aware of</p> <p>14 whether any of those entities had any DEA</p> <p>15 enforcement action against them?</p> <p>16 A. No, I was not aware.</p> <p>17 Let me rephrase that. I don't</p> <p>18 recall being aware of any, right. I just...</p> <p>19 (Sotto voce discussion.)</p> <p>20 (Mallinckrodt-Saffold</p> <p>21 Exhibit 34 was marked for</p> <p>22 identification.)</p> <p>23 QUESTIONS BY MS. KEECH:</p> <p>24 Q. I'm handing you what's been</p> <p>25 marked as Exhibit 34, bearing</p>	<p>1 Q. Do you recall ever having that</p> <p>2 conversation with Karen?</p> <p>3 A. No, I don't recall it.</p> <p>4 Q. And in 2011, you were in a</p> <p>5 customer service capacity. Is that correct?</p> <p>6 A. Yes.</p> <p>7 Q. Was anyone, to your knowledge,</p> <p>8 in customer service receiving any kind of</p> <p>9 compensation that was tied to sales numbers?</p> <p>10 A. I don't recall.</p> <p>11 Q. Is it possible?</p> <p>12 A. You know, I don't recall.</p> <p>13 Q. Okay. What about your personal</p> <p>14 compensation scheme?</p> <p>15 A. I don't recall what my scheme</p> <p>16 was that year.</p> <p>17 Q. Okay. But fair to say in 2011,</p> <p>18 you were working with Karen Harper in some</p> <p>19 capacity to assist with compliance?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And do you see any</p> <p>22 conflict with assisting Karen with compliance</p> <p>23 and determining -- strike that.</p> <p>24 Do you see any conflict with</p> <p>25 assisting with compliance while working in a</p>
Page 187	Page 189
<p>1 MNK-T1_0004604436.</p> <p>2 A. Okay.</p> <p>3 Q. Do you recognize this document?</p> <p>4 A. No.</p> <p>5 Q. Okay. Any reason to doubt its</p> <p>6 authenticity?</p> <p>7 A. No.</p> <p>8 Q. Okay. So this is an e-mail</p> <p>9 from Karen Harper dated July 13th, 2011, to</p> <p>10 Steven Becker with a CC to a number of</p> <p>11 people, including you.</p> <p>12 And Karen sends a list of</p> <p>13 Mallinckrodt's SKUs noting products Masters</p> <p>14 will not be receiving in the future given</p> <p>15 current SOM program restrictions. Karen then</p> <p>16 writes -- this is on the first page,</p> <p>17 paragraph 3 -- can you read what she says</p> <p>18 beginning with the paragraph with your name?</p> <p>19 A. "George Saffold and I are</p> <p>20 meeting Friday to identify improvements in</p> <p>21 our internal communications system from the</p> <p>22 time customer notification occurs to placing</p> <p>23 restrictions on the customer account and then</p> <p>24 to ensure that systems support the customer</p> <p>25 account restrictions."</p>	<p>1 customer service capacity?</p> <p>2 A. No. It's kind of the opposite.</p> <p>3 Part of service is servicing the customer in</p> <p>4 a compliant manner.</p> <p>5 Q. Do you know whether the issue</p> <p>6 was ever raised internally at Mallinckrodt</p> <p>7 about whether there was a conflict in</p> <p>8 customer service being involved in Suspicious</p> <p>9 Order Monitoring?</p> <p>10 A. I wouldn't know.</p> <p>11 Q. Do you know whether the DEA</p> <p>12 ever raised this as an issue?</p> <p>13 A. I wouldn't know.</p> <p>14 Q. Okay.</p> <p>15 (Sotto voce discussion.)</p> <p>16 (Mallinckrodt-Saffold</p> <p>17 Exhibit 35 was marked for</p> <p>18 identification.)</p> <p>19 QUESTIONS BY MS. KEECH:</p> <p>20 Q. I'm handing you what's been</p> <p>21 marked as Exhibit 35, bearing Bates number</p> <p>22 MNK-T1_0004155087.</p> <p>23 (Document review by witness.)</p> <p>24 QUESTIONS BY MS. KEECH:</p> <p>25 Q. All right. After reviewing</p>

Page 190	Page 192
<p>1 that e-mail, does this refresh your 2 recollection of anything? 3 A. No. 4 Q. No? Okay. Don't recognize 5 this e-mail? 6 A. No, I don't. 7 Q. Do you have any reason to doubt 8 its authenticity? 9 A. No, I don't. 10 Q. So this e-mail thread discusses 11 a discrepancy in ordering. At the top of the 12 e-mail you sent an e-mail dated January 23rd, 13 2012, to Jim Rausch regarding a forward of an 14 ABC order entry issue, customer requests 15 corrective actions. 16 So this e-mail concerns a large 17 error in product shipment to 18 AmerisourceBergen. AmerisourceBergen's 19 purchase order was for 42 and the quantity 20 ordered was 732, and I'm referring to page 3 21 of this document about halfway down in the 22 e-mail from Jeff Angeloni to Brenda Lindsey 23 and others. 24 A. I'm sorry, I'm not finding... 25 oh, thanks. Okay. Thank you.</p>	<p>1 as described is probably, you know, the only 2 instance. 3 Q. Okay. 4 (Mallinckrodt-Saffold 5 Exhibit 36 was marked for 6 identification.) 7 QUESTIONS BY MS. KEECH: 8 Q. I'm handing you what's been 9 marked as Exhibit 36. 10 A. Thank you. 11 Q. Bearing the Bates 12 MNK-T1_0007823812. And this is an e-mail 13 from Karen Harper to JoAnne Levy with a CC to 14 you dated September 15th, 2009. Subject 15 line: Shipment of oxycodone to DSM prior to 16 222 form receipt. 17 (Document review by witness.) 18 A. Yes, I see it. 19 QUESTIONS BY MS. KEECH: 20 Q. Okay. Have you ever seen this 21 document before, that you recall? 22 A. Not that I recall. 23 Q. Any reason to doubt its 24 authenticity? 25 A. No.</p>
<p style="text-align: center;">Page 191</p> <p>1 Q. Okay. And at the top of the 2 e-mail thread you write to Jim, "Can you 3 respond to all on copy outlining the 4 corrective actions in place." 5 A. Yes. 6 Q. Do you know what, if any, 7 corrective actions happened? 8 A. I really don't recall this 9 situation. 10 Q. Okay. If you don't recall this 11 particular instance, do you recall whether 12 there was a procedure in general for when 13 more of a product shipped than what was 14 ordered? 15 A. A procedure? No, I don't 16 think -- you know, I think that was highly 17 anomalous, so I don't know if we'd have like 18 a procedure. 19 Q. So fair to say that this didn't 20 happen very frequently? 21 A. Yes. 22 Q. Okay. And how would you define 23 not very frequently? 24 A. As in -- as in probably this 25 being -- as in thinking that this situation</p>	<p style="text-align: center;">Page 193</p> <p>1 Q. Okay. And you've had an 2 opportunity to review this e-mail. It's an 3 e-mail regarding shipment of oxycodone 4 without first having a 222 form receipt. Is 5 that correct? 6 A. Yes. 7 Q. And Karen writes at the top of 8 the e-mail, paragraph two -- can you read 9 that sentence? 10 A. "The upside is that DEA Quota 11 Section indicated DSM now has quota to keep 12 the material. However, this does not absolve 13 us of the fact that we shipped without a DEA 14 222 form." 15 Q. And is it permissible to ship 16 this type of product without a 222 form? 17 A. No. 18 Q. Do you know when this incident 19 was reported to the DEA? 20 A. I don't have knowledge of it, 21 but just even reading this e-mail, it really 22 appears it was. 23 Q. And fair to say that was an 24 error on Mallinckrodt's part to ship without 25 a 222 form in this instance?</p>

	Page 194	Page 196
1	A. I don't know the specific	1 MS. KEECH: Okay. I think
2	circumstances, but I think so, yes.	2 that's all I have for now. I'm going
3	Q. Okay. You testified earlier	3 to turn it over to Tennessee, but I
4	that Jim Rausch reviewed peculiar order	4 may have some questions later on this
5	reports. Is that correct?	5 afternoon.
6	A. Yes.	6 THE WITNESS: Okay.
7	Q. Okay. Are you aware of whether	7 MS. KEECH: Do you want to take
8	customer service managers reviewed every	8 a break before we transition?
9	peculiar or unusual order that was identified	9 MR. GASTEL: Yeah, can we just
10	by Mallinckrodt?	10 take five minutes?
11	A. Yes. My understanding is that	11 MS. KEECH: Sure, okay. Thank
12	was -- for a period of time, that was	12 you.
13	required.	13 THE VIDEOGRAPHER: Off the
14	Q. Okay. And was that required by	14 record, 2:46.
15	managers or also customer service	15 (Recess taken, 2:46?p.m. to
16	representatives?	16 2:53?p.m.)
17	MR. BERG: Object to form.	17 THE VIDEOGRAPHER: All right,
18	A. I think it was required by	18 stand by. The time is 2:53. Back on
19	compliance for customer service to review	19 the record.
20	these orders.	20 EXAMINATION
21	QUESTIONS BY MS. KEECH:	21 QUESTIONS BY MR. GASTEL:
22	Q. And who within customer service	22 Q. Good afternoon, Mr. Saffold.
23	had the responsibility to review them?	23 MR. GASTEL: Before I get
24	A. So Jim had the responsibility	24 started, I lodge a standard objection.
25	to review them.	25 Mr. O'Connor has been letting me just
	Page 195	Page 197
1	Q. Okay.	1 say the standard objection. Is that
2	A. He -- which would not preclude	2 okay if I lodge my standard objection?
3	him from asking agents, hey, you know, look	3 MR. BERG: It is okay.
4	at this -- again, who are more familiar with	4 QUESTIONS BY MR. GASTEL:
5	the customers in some instances. You know,	5 Q. Subject to that objection, I
6	tell me -- talk to me about this order, what	6 represent plaintiffs who are in a Tennessee
7	are your thoughts, who do I contact, you	7 lawsuit involving slightly different claims
8	know, with questions and those things.	8 than the lawsuit that Ms. Keech was asking
9	Q. So it was the managers'	9 you questions about earlier. Before I get
10	ultimate responsibility, but it wasn't	10 started about sort of Tennessee-specific
11	uncommon for them to defer to representatives	11 stuff, I want to ask just a couple of
12	if they had questions?	12 preliminary questions.
13	A. Certainly it was the managers'	13 What is your full residential
14	ultimate responsibility. I'm not sure if	14 address, Mr. Saffold?
15	they deferred or they just asked questions.	15 A. 7013 Reatta Court, and that's
16	Q. Okay.	16 R-E-A-T-T-A, Court, North Richland Hills,
17	(Sotto voce discussion.)	17 Texas 76182.
18	QUESTIONS BY MS. KEECH:	18 Q. And how long have you lived
19	Q. In the reports that Jim Rausch	19 there?
20	reviewed --	20 A. Since May of '17.
21	A. Yes.	21 Q. And who lives there with you?
22	Q. -- internally for peculiar	22 A. My wife, Sarah, and my two
23	orders, do you know whether those were	23 sons, Spencer and Max.
24	submitted to the DEA?	24 Q. And do you have any plans to
25	A. I don't know.	25 move in the foreseeable future?

	Page 198	Page 200
1	A. No.	1 Q. Got it.
2	Q. Prior to that, were you living	2 And you're not currently
3	in or near St. Louis, Missouri?	3 employed by Mallinckrodt, correct?
4	A. Yes.	4 A. Correct.
5	Q. And that's where you were	5 Q. You're currently employed
6	living when you were working with Covidien	6 where?
7	and Mallinckrodt?	7 A. At VF Corporation, Dickies, in
8	A. Yes.	8 Fort Worth, Texas.
9	Q. Earlier today you had mentioned	9 Q. So you had to take time off of
10	that in preparation for today's deposition,	10 work yesterday and today for this deposition,
11	you had met two times with counsel.	11 correct?
12	Do you recall that testimony?	12 A. Yes.
13	A. Yes.	13 Q. Is Mallinckrodt paying for your
14	Q. How long were those meetings?	14 time today?
15	A. A few hours.	15 A. No.
16	Q. When was the first meeting?	16 Q. Did you take vacation time from
17	A. In December, I think. Yeah.	17 your current employer?
18	Q. December of --	18 A. Yes.
19	A. Oh, wait. Was it -- you know	19 Q. Do you know anything specific
20	what, actually, it was either in December or	20 about the Tennessee litigation?
21	January. I can't remember which. I'm sorry.	21 A. No.
22	Q. That's all right.	22 Q. Have you ever reviewed the
23	And was that an in-person	23 complaints -- any of the complaints filed in
24	interview or was that a conference call?	24 the Tennessee litigation?
25	A. It was in person.	25 A. No.
	Page 199	Page 201
1	Q. Was it here in Texas?	1 Q. In your work for Mallinckrodt
2	A. Yes.	2 or Covidien, did you ever travel to the state
3	Q. And what counsel was present?	3 of Tennessee for your work?
4	A. Counsel from Ropes & Gray.	4 A. I don't recall. Oh, I do
5	Q. Is it the same counsel here	5 recall one instance. I went to Memphis to
6	today?	6 meet with a 3PL, which is a third-party
7	A. No. There's some same and some	7 logistics provider, who handled some medicine
8	different.	8 for us, a brand that we had just purchased,
9	Q. And then when was the second	9 and just to meet with them in Memphis or kind
10	meeting?	10 of outside Memphis. So -- I think that's the
11	A. Yesterday.	11 only specific time I remember. There could
12	Q. And approximately how long was	12 have been others.
13	that meeting?	13 Q. Was that third-party vendor
14	A. A few hours.	14 FedEx?
15	Q. When you say "a few hours," do	15 A. No. It was a division of
16	you mean one to two hours, three to four	16 Cardinal, but very far down because it was
17	hours?	17 like in the 3PL and they're newly acquired by
18	A. Four-ish. Four.	18 Cardinal and the drug was intrathecal
19	Q. And I assume that that meeting	19 therapeutic medicine.
20	was here in Texas?	20 Q. What do you mean by 3PL?
21	A. Yes.	21 A. A third-party logistics
22	Q. And that was a meeting with	22 provider, so that means they -- like they
23	counsel who are present today?	23 pick, pack and ship on your behalf and they
24	A. Again, no. Some counsel.	24 keep the stuff in the warehouse for you so
25	Cassandra was there, present. Nick wasn't.	25 you don't have to own your own warehouse.

Page 202	Page 204
<p>1 Q. Okay. Do you have any 2 understanding of opioid prescription rates in 3 the state of Tennessee? 4 A. No. 5 Q. Do you recall ever reviewing 6 any news articles about the opioid epidemic 7 in Tennessee? 8 A. No. 9 Q. Do you have an understanding 10 that the opioid epidemic is more acute in 11 some parts of the country than other parts of 12 the country? 13 A. Yes. 14 Q. What parts of the country is it 15 your understanding where the opioid epidemic 16 is particularly acute? 17 A. I have a limited understanding. 18 I hear a lot about West Virginia, and then in 19 general, maybe not a part of the country, but 20 the description of rural areas, it seems more 21 acute. 22 Q. When you reference West 23 Virginia, do you recall any references to the 24 opioid epidemic being particularly acute in 25 Appalachian areas?</p>	<p>1 that you had heard of the term "Oxy Express." 2 Do you recall that? 3 A. I do. 4 Q. Do you know if that is a 5 reference to Interstate 75, which is an 6 interstate that runs through the state of 7 Florida up north? 8 A. That's my understanding, that 9 it's an interstate that runs from Florida to 10 kind of the northeast corridor. I'm not sure 11 if I would know the interstate number. 12 Q. Sure. 13 Do you have an understanding 14 that that interstate runs through eastern 15 Tennessee? 16 A. No, I don't know that. 17 Q. So I think, if I'm 18 understanding your testimony correctly, you 19 understand that the Oxy Express started in 20 Florida? 21 A. Yes. 22 Q. And it ran up a corridor along 23 an interstate through the northwest? 24 A. Through the northeast. 25 Q. Northeast.</p>
Page 203	Page 205
<p>1 A. Yes. 2 Q. Are you aware that eastern 3 Tennessee is kind of the southern portion of 4 the Appalachia region? 5 A. Not really. I probably should 6 be. 7 Q. It's all right. If people ask 8 me about geography in Texas, I'd have to 9 plead ignorance too, so it's okay. 10 Have you ever reviewed any 11 materials published by the Tennessee 12 Department of Health? 13 A. Not that I can recall. 14 Q. In your time with Mallinckrodt, 15 did you ever have occasion to review 16 IMS Health data regarding opioid prescription 17 rates? 18 A. No. I can't recall ever 19 looking at any data, no. 20 Q. Do you recall during your time 21 with Mallinckrodt ever discussing any 22 specific pill mill operations in the state of 23 Tennessee? 24 A. No. 25 Q. You testified earlier today</p>	<p>1 A. Yes. 2 Q. But you don't know the specific 3 states that it touched or the areas that it 4 went through? 5 A. No. 6 Q. In your role as director of 7 global customer service, did you interact 8 with law enforcement officials? 9 A. No. 10 Q. Do you ever recall talking to a 11 police officer from Morristown, Tennessee? 12 A. No, I don't. 13 Q. Do you ever recall any 14 discussions at Mallinckrodt regarding an 15 inquiry made from a police officer in 16 Morristown, Tennessee? 17 A. No, I don't. 18 (Discussion off the 19 stenographic record.) 20 (Mallinckrodt-Saffold 21 Exhibit 37 was marked for 22 identification.) 23 QUESTIONS BY MR. GASTEL: 24 Q. I'm going to hand you a 25 document that we'll mark as Exhibit 37.</p>

Page 206	Page 208
<p>1 A. Thank you.</p> <p>2 Q. Do you see that this is an</p> <p>3 e-mail dated April 21st, 2011, from Mike</p> <p>4 Santowski to you?</p> <p>5 A. Yes.</p> <p>6 Q. Do you recall receiving this</p> <p>7 e-mail?</p> <p>8 MR. MILLER: Is there a Bates</p> <p>9 number on this document?</p> <p>10 MR. GASTEL: Sure. It's</p> <p>11 MNK-T1_0007114309.</p> <p>12 QUESTIONS BY MR. GASTEL:</p> <p>13 Q. And he's forwarding you an</p> <p>14 e-mail that he had sent, Mr. Santowski had</p> <p>15 sent, to Blanche Eder?</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Who is Blanche Eder?</p> <p>19 A. I believe Blanche was an</p> <p>20 administrative assistant, but I'm not sure to</p> <p>21 whom.</p> <p>22 Q. And it says: Blanche, for</p> <p>23 Monday's EC meeting. I will have George make</p> <p>24 copies for Monday.</p> <p>25 Did I read that correctly?</p>	<p>1 because I had an admin and I know there were</p> <p>2 times where Michael didn't have an admin, so</p> <p>3 he, you know, asked me to have my admin do</p> <p>4 stuff because she -- you know, I reported to</p> <p>5 him so he kind of shared her with me.</p> <p>6 Q. And is Doris your admin?</p> <p>7 A. She was, yes.</p> <p>8 Q. She was at that time.</p> <p>9 Let's flip to the PowerPoint</p> <p>10 presentation that's attached to this e-mail.</p> <p>11 A. Sure.</p> <p>12 Q. Do you see how on the first</p> <p>13 page, the cover page, it is entitled</p> <p>14 Mallinckrodt Controlled Substance Suspicious</p> <p>15 Order Monitoring Program?</p> <p>16 A. I do.</p> <p>17 Q. And it has a note here that</p> <p>18 it's for the presentation for executive</p> <p>19 committee of April 25th, 2011, right?</p> <p>20 A. Yes.</p> <p>21 Q. Would the executive committee</p> <p>22 be the higher-up executives at Covidien</p> <p>23 Mallinckrodt?</p> <p>24 A. Yes.</p> <p>25 Q. Would that be C-level --</p>
<p>1 A. Yes.</p> <p>2 Q. Is "EC meeting" a reference to</p> <p>3 an executive committee meeting?</p> <p>4 A. Yes.</p> <p>5 Q. And who would typically attend</p> <p>6 an executive committee meeting?</p> <p>7 A. I don't know.</p> <p>8 Q. Would you ever attend executive</p> <p>9 committee meetings?</p> <p>10 A. Only as an invited guest and</p> <p>11 usually to maybe do a presentation and then</p> <p>12 usually leave.</p> <p>13 Q. Do you recall attending the one</p> <p>14 that's referenced in this e-mail, April</p> <p>15 of 2011? You can feel free to look through</p> <p>16 the document.</p> <p>17 (Document review by witness.)</p> <p>18 A. No. I don't recall attending</p> <p>19 this meeting.</p> <p>20 QUESTIONS BY MR. GASTEL:</p> <p>21 Q. Do you know why Mr. Santowski</p> <p>22 might have asked you to make copies of this</p> <p>23 or have you have Doris make copies of this</p> <p>24 presentation?</p> <p>25 A. I don't know for sure, but</p>	<p>1 C suite level people?</p> <p>2 A. I don't know the -- and I don't</p> <p>3 recall the specific members of the executive</p> <p>4 committee.</p> <p>5 Q. But it would be people higher</p> <p>6 than you in the organizational chart?</p> <p>7 A. Yes.</p> <p>8 Q. Would it be higher than</p> <p>9 people -- than Mr. Santowski?</p> <p>10 A. I really don't know if he was</p> <p>11 executive committee or not.</p> <p>12 Q. Sure.</p> <p>13 Will you flip to page 4 of this</p> <p>14 PowerPoint presentation?</p> <p>15 A. Sure.</p> <p>16 Q. And do you see that it's</p> <p>17 entitled Florida Distribution of Oxycodone?</p> <p>18 A. Yes.</p> <p>19 Q. And it says: 98 of the top 100</p> <p>20 doctors dispensing oxycodone nationally are</p> <p>21 in Florida. By far, more oxycodone is</p> <p>22 dispensed in the state of Florida than in the</p> <p>23 remaining states combined.</p> <p>24 Did I read that correctly?</p> <p>25 A. Yes.</p>

Page 210	Page 212
<p>1 Q. And, again, there's a reference 2 here that the data comes from the Florida 3 governor's press office of March 28, 2011. 4 Did I read that correctly?</p> <p>5 A. Yes.</p> <p>6 Q. And earlier today you went 7 through an e-mail with Ms. Keech showing that 8 Mallinckrodt eventually suspended orders to 9 five of its distributor customers.</p> <p>10 Do you remember that e-mail?</p> <p>11 A. Yes.</p> <p>12 Q. And those five were KeySource, 13 Masters, Harvard, Cedardale and Sunrise, 14 right?</p> <p>15 A. Yes.</p> <p>16 Q. And that was related to 17 diversion activity going on in the state of 18 Florida, correct?</p> <p>19 A. I don't know the --</p> <p>20 MR. BERG: Object to form.</p> <p>21 THE WITNESS: Sorry.</p> <p>22 A. I don't know the specifics 23 around these accounts and why they're 24 suspended.</p> <p>25 --oOo--</p>	<p>1 Q. A reference to Cardinal paying 2 a \$34 million fine for actions -- in having 3 their license suspended at three distribution 4 centers?</p> <p>5 Do you see that?</p> <p>6 A. Yes.</p> <p>7 Q. And there's also a reference to 8 McKesson paying more than \$13 million to 9 settle claims that it failed to report 10 suspicious sales of prescription medications.</p> <p>11 Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. And those, I think you 14 referenced earlier today, are the Big Three?</p> <p>15 A. Yes.</p> <p>16 Q. And they remained the Big Three 17 from 2008 to the time that you left your role 18 at Mallinckrodt, right?</p> <p>19 MR. BERG: Objection to form.</p> <p>20 A. Yes.</p> <p>21 QUESTIONS BY MR. GASTEL:</p> <p>22 Q. In other words, they were the 23 three largest customers of Mallinckrodt for 24 controlled substances, right?</p> <p>25 A. Yeah, they're the three largest</p>
<p>1 QUESTIONS BY MR. GASTEL:</p> <p>2 Q. But it sounded like you had 3 some role in implementing their -- the 4 suspension of sales of controlled substances 5 to those five organizations in 2011?</p> <p>6 MR. BERG: Object to form.</p> <p>7 A. I don't think I really had a 8 role in implementing the suspension of any 9 accounts.</p> <p>10 QUESTIONS BY MR. GASTEL:</p> <p>11 Q. Will you flip to page 6?</p> <p>12 A. Yes.</p> <p>13 Q. You see that this slide is 14 entitled DEA Distributor Initiative, 2008?</p> <p>15 A. Yes.</p> <p>16 Q. And it says: DEA suspends 17 licenses of distributors for not maintaining 18 effective controls against diversion of 19 controlled substances.</p> <p>20 Did I read that correctly?</p> <p>21 A. Yes.</p> <p>22 Q. And there's a reference to an 23 AmerisourceBergen facility in Orlando, 24 Florida, correct?</p> <p>25 A. Yes.</p>	<p>1 customers of Mallinckrodt Pharmaceuticals.</p> <p>2 Q. Will you flip to the next page?</p> <p>3 There's a reference to Masters 4 Pharmaceutical.</p> <p>5 Do you see that?</p> <p>6 A. I do.</p> <p>7 Q. And it says Masters is a 8 Mallinckrodt distributor customer?</p> <p>9 A. Yes.</p> <p>10 Q. And it says: Masters sold more 11 than 4 million doses of hydrocodone, 12 phentermine and alprazolam to internet 13 pharmacies between 2005 to 2008 without 14 reporting the sales to the DEA.</p> <p>15 Did I read that correctly?</p> <p>16 A. Yes.</p> <p>17 Q. It says: Although Masters 18 reported suspicious orders during the 19 2005-2008 period in question, the DEA 20 believed that some orders placed by 10 21 pharmacies should have been reported as 22 suspicious.</p> <p>23 Did I read that correctly?</p> <p>24 A. Yes.</p> <p>25 Q. It says they were fined</p>

Page 214	Page 216
<p>1 \$500,000, right?</p> <p>2 A. Yes.</p> <p>3 Q. And this e-mail presentation</p> <p>4 was apparently given to Mallinckrodt's</p> <p>5 executive team just a few months before the</p> <p>6 suspension went into effect for KeySource,</p> <p>7 Masters, Harvard, Cedardale and Sunrise,</p> <p>8 right?</p> <p>9 MR. BERG: Object to form.</p> <p>10 A. I'd have to kind of</p> <p>11 cross-reference the dates. I don't really</p> <p>12 recall -- I don't recall this presentation or</p> <p>13 the circumstances around the suspension of</p> <p>14 the five distributors you just named.</p> <p>15 QUESTIONS BY MR. GASTEL:</p> <p>16 Q. Sure. But the date on this</p> <p>17 presentation is April of 2011, right?</p> <p>18 A. Yes.</p> <p>19 Q. And the date of the e-mail that</p> <p>20 you were looking at with Ms. Keech earlier</p> <p>21 was July of 2011, right?</p> <p>22 A. Yes.</p> <p>23 Q. So if the dates of these</p> <p>24 documents are correct, then it appears that</p> <p>25 this was given just a few months prior to</p>	<p>1 Q. Are you aware that Mallinckrodt</p> <p>2 eventually entered into its own memorandum of</p> <p>3 understanding with the DEA?</p> <p>4 A. No.</p> <p>5 Q. You weren't aware of</p> <p>6 Mallinckrodt entering into such an agreement</p> <p>7 with the DEA?</p> <p>8 A. No, I'm not.</p> <p>9 Q. Would it surprise you to learn</p> <p>10 that that were true?</p> <p>11 A. I mean, not, you know, I'm</p> <p>12 going to be startled or alarmed, but yes.</p> <p>13 Q. And I know you testified</p> <p>14 earlier that you were on the Suspicious Order</p> <p>15 Monitoring steering committee, right?</p> <p>16 A. Yes.</p> <p>17 Q. And you would occasionally</p> <p>18 attend meetings, right?</p> <p>19 A. Yes.</p> <p>20 Q. I'm going to hand you a</p> <p>21 document that we're going to mark as</p> <p>22 Exhibit 38.</p> <p>23 (Mallinckrodt-Saffold</p> <p>24 Exhibit 38 was marked for</p> <p>25 identification.)</p>
<p style="text-align: center;">Page 215</p> <p>1 Mallinckrodt suspending sales of controlled</p> <p>2 substances to those five distributors, right?</p> <p>3 A. Yes.</p> <p>4 Q. So as early as 2011,</p> <p>5 Mallinckrodt knew that its distributors were</p> <p>6 getting in trouble with the DEA for their</p> <p>7 failure to maintain effective controls</p> <p>8 against diversion.</p> <p>9 Would you agree with that</p> <p>10 statement?</p> <p>11 MR. BERG: Object to form.</p> <p>12 A. As early as 2011, Mallinckrodt</p> <p>13 knew that -- yes.</p> <p>14 QUESTIONS BY MR. GASTEL:</p> <p>15 Q. Do you know how many</p> <p>16 Mallinckrodt orders to these distributors</p> <p>17 were reported to the DEA during this time</p> <p>18 period as suspicious?</p> <p>19 A. No.</p> <p>20 Q. Would you ask Karen Harper that</p> <p>21 question if you needed to know the answer to</p> <p>22 it?</p> <p>23 A. If I had needed to know the</p> <p>24 answer to that question, I would have asked</p> <p>25 Karen Harper, yes.</p>	<p style="text-align: center;">Page 217</p> <p>1 QUESTIONS BY MR. GASTEL:</p> <p>2 Q. And this is an e-mail from</p> <p>3 Jennifer Buist to John Gillies dated</p> <p>4 December 12, 2012, 12/12/12. And attached to</p> <p>5 it is some steering committee notes for that</p> <p>6 date.</p> <p>7 MR. MILLER: Is there a Bates</p> <p>8 number on the document?</p> <p>9 MR. GASTEL: Sure. It's</p> <p>10 MNK-T1_0006967774.</p> <p>11 QUESTIONS BY MR. GASTEL:</p> <p>12 Q. Do you see that, sir?</p> <p>13 A. Yes.</p> <p>14 Q. Do you recall attending a</p> <p>15 meeting of the steering committee on</p> <p>16 December 12, 2012?</p> <p>17 A. No, I don't.</p> <p>18 Q. Do you ever recall the steering</p> <p>19 committee -- if you flip to the last page of</p> <p>20 this document, sir, there is a chart under</p> <p>21 Jen Buist Statistics.</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. And then there's a chart and it</p> <p>25 says Order Lines Processed and Order Lines</p>

<p style="text-align: right;">Page 218</p> <p>1 Failed.</p> <p>2 Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. And then for a period from</p> <p>5 March 2012 to November 2012, it adds up the</p> <p>6 order lines processed and the order lines</p> <p>7 failed.</p> <p>8 Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. Your customer service</p> <p>11 department was responsible for processing the</p> <p>12 order lines, right?</p> <p>13 A. No. I mean, if we entered a</p> <p>14 manual order, yes, but there were a series of</p> <p>15 edits and a lot of electronic orders that</p> <p>16 then ran edits and -- that we didn't really</p> <p>17 do or own.</p> <p>18 Q. Sure. And we might be talking</p> <p>19 past one another.</p> <p>20 A. Okay.</p> <p>21 Q. Happens all the time. I might</p> <p>22 ask a bad question. I ask -- I do it all the</p> <p>23 time. But what I mean is that when an order</p> <p>24 line gets shipped, it's shipped by the</p> <p>25 customer service department, right?</p>	<p style="text-align: right;">Page 220</p> <p>1 Q. And then eventually, if those</p> <p>2 orders pass all of that, that's when they're</p> <p>3 released for shipment?</p> <p>4 A. Yes. So after an order passes</p> <p>5 all through those, then the order -- the</p> <p>6 items on the order, then it looks at -- the</p> <p>7 system will look at availability of the</p> <p>8 product. And if the product is available in</p> <p>9 the distribution center, then there's -- the</p> <p>10 order activity rules govern this. So then</p> <p>11 there's a -- a pick is generated. So then</p> <p>12 the person in the distribution center goes</p> <p>13 and picks the product and they -- there's a</p> <p>14 process called pick confirm, and then they</p> <p>15 put it in the packing area and there's a</p> <p>16 practice called pack confirm. So it goes</p> <p>17 through all these steps.</p> <p>18 And then after it's</p> <p>19 pack-confirmed, there's kind of a count to</p> <p>20 make sure everything matched up, and then</p> <p>21 following that, there's a ship confirm, which</p> <p>22 basically means we put this on the truck.</p> <p>23 And then that generates an invoice.</p> <p>24 Q. And then once it's on the</p> <p>25 truck, it's released?</p>
<p style="text-align: right;">Page 219</p> <p>1 A. No. An order is shipped -- I</p> <p>2 mean, not to -- an order is shipped by our</p> <p>3 shipping department, right, by our facility</p> <p>4 in -- where the product is kept. Customer</p> <p>5 service does not ship orders.</p> <p>6 Q. Then who releases the order to</p> <p>7 be shipped?</p> <p>8 A. Well, if the order is</p> <p>9 electronic, it flows through the system. If</p> <p>10 an order is manual, customer service enters</p> <p>11 the order and then if it passes the edits, it</p> <p>12 will just flow through. And if an order has</p> <p>13 field edits, typically it's customer service</p> <p>14 that can release, like, something that was</p> <p>15 held. But there may be others as well.</p> <p>16 Q. Sure.</p> <p>17 And what do you mean by passing</p> <p>18 edits?</p> <p>19 A. So there's all kinds of edits</p> <p>20 that run over an order in the order</p> <p>21 management system; unit of measure checks,</p> <p>22 address matches, 222 number, you know,</p> <p>23 restricted and unrestricted, a lot of edits</p> <p>24 like that. So we kind of refer to those as</p> <p>25 order integrity checks.</p>	<p style="text-align: right;">Page 221</p> <p>1 A. Well, I don't know -- I mean,</p> <p>2 it's -- I don't know if there's like a</p> <p>3 release -- I mean, once it's on the truck</p> <p>4 it's already -- you know, it's gone through</p> <p>5 those processes I named.</p> <p>6 Q. Sure.</p> <p>7 But once it's on the truck,</p> <p>8 it's sort of out of Mallinckrodt's hands and</p> <p>9 going to wherever it's supposed to go, right?</p> <p>10 A. Sort of, but not really.</p> <p>11 Because we also -- we also make sure that --</p> <p>12 made sure that then it was delivered to the</p> <p>13 right spot, including the signature of the</p> <p>14 person and checking that up against a list of</p> <p>15 who was authorized to receive that product</p> <p>16 and ensured that happened.</p> <p>17 And at that point I would say,</p> <p>18 after we know they signed it, it was signed</p> <p>19 for by the right person, it was delivered,</p> <p>20 then I think it's fair to say, then it's</p> <p>21 totally out of ours.</p> <p>22 Q. But assuming that everything is</p> <p>23 processed correctly, it's delivered</p> <p>24 correctly, Mallinckrodt doesn't have the</p> <p>25 hands on its product after it's on the truck?</p>

Page 222	Page 224
<p>1 A. Yes, I think that's fair to 2 say.</p> <p>3 Q. And then during that process 4 that you described, at some point it leaves 5 customer service's hands, right, and 6 essentially gets -- if I'm understanding your 7 testimony correctly -- placed in the hands of 8 the delivery production team, right?</p> <p>9 A. Yes. Yeah.</p> <p>10 Q. And then -- but if I'm 11 understanding your testimony correctly, all 12 of the lines that come in for an order go 13 through that customer service system, right?</p> <p>14 A. No. I mean, so, you know, 15 customer service is only going to see orders 16 that we either enter or that have not passed 17 those edits and then are on an exception 18 report. You know, exception report for any 19 reason.</p> <p>20 If an electronic order, which 21 is what probably 90% of what was ordered was, 22 if an electronic order went from EDI through 23 CSOS, everything was good, we had the 24 product, it went down to the DC, we would -- 25 we wouldn't really see that order. It</p>	<p>1 if you get one electronic order it's going to 2 be a lot more product, typically.</p> <p>3 Q. Sure.</p> <p>4 So if I'm understanding your 5 testimony correctly, the majority of product 6 that gets shipped in the time period of 2012 7 to the time you left Mallinckrodt would have 8 been ordered electronically.</p> <p>9 A. Yes.</p> <p>10 Q. Do you have an understanding of 11 approximately how many order lines hit the 12 algorithm?</p> <p>13 MR. BERG: Object to form.</p> <p>14 A. No. Well, are you referring to 15 the Suspicious Order Monitoring algorithm?</p> <p>16 QUESTIONS BY MR. GASTEL:</p> <p>17 Q. Yes.</p> <p>18 A. No. I don't really have a lot 19 of information about how that algorithm 20 functions.</p> <p>21 Q. Sure.</p> <p>22 (Mallinckrodt-Saffold 23 Exhibit 39 was marked for 24 identification.)</p> <p>25 --oOo--</p>
<p>1 wouldn't be fair to say it was in customer 2 service.</p> <p>3 Q. And then if it's not flagged by 4 the SOM algorithm, the electronic order --</p> <p>5 A. Yes.</p> <p>6 Q. -- it would go through the 7 process that you described of being packaged 8 and shipped and put on the truck, correct?</p> <p>9 A. Yes.</p> <p>10 Q. And I think that you testified 11 that the vast majority of the orders are 12 electronic, correct?</p> <p>13 A. Yes.</p> <p>14 Q. Was that true from the time 15 period of 2013 through present?</p> <p>16 A. I certainly couldn't speak to 17 the present today.</p> <p>18 Q. Sure.</p> <p>19 A. But I can speak through my 20 tenure at Mallinckrodt. I don't know if -- 21 the number of orders, but I could say the 22 quantity of product. Does that kind of -- 23 because you're going to get -- onesie-twosies 24 are more likely to be manual, so you might 25 get a lot of onesie-twosie orders, but then</p>	<p>1 QUESTIONS BY MR. GASTEL:</p> <p>2 Q. I'm going to hand you a 3 document that has been marked as Exhibit 39. 4 And this is an e-mail from Matt Bell dated 5 October 8th, 2013, sent to a variety of 6 people. You're CC'd on it. You'll see that 7 you're the last name on the second-to-last -- 8 third-to-last CC line.</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 MR. MILLER: Sorry. Is there a 12 Bates number on the document?</p> <p>13 MR. GASTEL: MNK-T1_0004291190.</p> <p>14 QUESTIONS BY MR. GASTEL:</p> <p>15 Q. And the subject is Oxycodone 16 Orders.</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. And it's a long e-mail chain, 20 but it starts, if you flip back to the 21 Bates-numbered page ending in 1193, it starts 22 with this e-mail from Jacob Longenecker on 23 October 3rd, 2013.</p> <p>24 Do you see that?</p> <p>25 A. Yes.</p>

Page 226	Page 228
<p>1 Q. And it says: As we previously 2 discussed, we should see large oxy orders 3 today from McKesson and ABC. These orders 4 can be spaced out based on their historical 5 demand.</p> <p>6 Did I read that correctly?</p> <p>7 A. Yes.</p> <p>8 Q. And then if you flip to the 9 next page after the chart, this is a 10 continuation of that same e-mail.</p> <p>11 It says: Jennifer, these 12 orders will certainly set off a flag on your 13 end. Please allow the orders to process.</p> <p>14 Did I read that correctly?</p> <p>15 A. Yes.</p> <p>16 Q. And if you go back to the 17 e-mail, the Jennifer referenced on the e-mail 18 is Jennifer Buist.</p> <p>19 Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. So am I correctly interpreting 22 this document that when Jacob Longenecker 23 tells Jennifer that the orders are going to 24 set off a flag on your end, that he's 25 signaling that these orders would hit the</p>	<p>1 you know, some of this and instead you're 2 selling this and we want to know why, right? 3 Because your forecast doesn't match and our 4 production people are making the wrong stuff, 5 so why are we getting this order?</p> <p>6 So I don't know -- because we 7 didn't want it to show on -- be backordered 8 if it's not really what we were intending to 9 sell. So -- and a lot of people on here 10 would have been, like, stakeholders in this 11 process.</p> <p>12 Q. Sure.</p> <p>13 And then going back to the 14 e-mail that you're covered on, it says: 15 Hello Jake and All. Updates below to the 16 shipping plan for the ABC and McKesson oxy 17 orders.</p> <p>18 Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. And it says: After meeting 21 with the customer service management today, 22 it was decided the best way to approach the 23 suggested shipment weeks in my chart below is 24 to add lines to each of the purchase orders 25 we have received from ABC and McKesson. Then</p>
Page 227	Page 229
<p>1 algorithm?</p> <p>2 MR. BERG: Object to form.</p> <p>3 A. I'm not sure of that. You 4 know, sub- -- I just can't be sure, because 5 we did -- you know, we're pretty good at 6 forecast and supply stuff and, so, you know, 7 especially with some of the people on copy, 8 they're kind of planning kind of guys, and I 9 know that they ran stuff to say, like, your 10 forecast is bad or this is too much demand 11 and we shouldn't have to fill it, just 12 because of from like a fill rate and service 13 and production planning.</p> <p>14 So I don't know if they're 15 really referring to the algorithm for 16 Suspicious Order Monitoring or not.</p> <p>17 QUESTIONS BY MR. GASTEL:</p> <p>18 Q. Do you know any other flag that 19 Jennifer Buist was responsible for other than 20 a Suspicious Order Monitoring flag?</p> <p>21 A. Yeah, yeah. So they -- I can't 22 really recall like a name for it, but just of 23 what we would call excessive demand, not 24 Suspicious Order Monitoring but just, hey, 25 you know, you told me you were going to sell,</p>	<p>1 divide the items on the purchase order lines 2 by an equal amount for however many weeks I 3 suggested that we ship the total SKU demand. 4 Finally, enter appropriate case quantities 5 and request dates for each line corresponding 6 to the regular shipment date for ABC or 7 McKesson.</p> <p>8 Did I read all that correctly?</p> <p>9 A. Yes.</p> <p>10 Q. Can you explain what any of 11 that means?</p> <p>12 A. No. I don't really recall 13 this, and I'm not sure I understand what he's 14 doing here.</p> <p>15 Q. And then -- but you don't -- 16 you see the reference to customer service 17 management?</p> <p>18 A. Yes.</p> <p>19 Q. Do you see any other customer 20 service folks on this e-mail other than you?</p> <p>21 A. Yes.</p> <p>22 Q. Who else is on there? Let me 23 strike that. Let me back up.</p> <p>24 Do you see any other people 25 from customer service management on here</p>

Page 230	Page 232
<p>1 other than you?</p> <p>2 A. I do.</p> <p>3 Q. And who are those people?</p> <p>4 A. Kris Quasebarth.</p> <p>5 Q. I don't mean to be rude, sir,</p> <p>6 but are you done?</p> <p>7 A. Oh, yeah. I'm sorry.</p> <p>8 Q. Okay. It's no problem. I just</p> <p>9 didn't know if you were still looking for</p> <p>10 names.</p> <p>11 What was Kris Quasebarth's</p> <p>12 role?</p> <p>13 A. He was manager of dosage and</p> <p>14 API customer service.</p> <p>15 Q. Okay, I'm sorry. I thought</p> <p>16 that only Mr. Rausch and Ms. Stewart were</p> <p>17 managers of dosage.</p> <p>18 A. So in 2013, neither Jim Rausch</p> <p>19 nor Cathy Stewart reported to me anymore and</p> <p>20 I don't think Jim was even part of the</p> <p>21 company anymore. So Kris was the</p> <p>22 replacement, and we consolidated API and</p> <p>23 dosage kind of under one manager and that was</p> <p>24 Kris.</p> <p>25 Q. Got it. Was he still there</p>	<p>1 Martinez and Ashley Kitchen.</p> <p>2 Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. It says McKesson Order</p> <p>5 Restrictions is the subject line.</p> <p>6 Do you see that?</p> <p>7 A. Yes.</p> <p>8 MS. WIDAS: Can you give the</p> <p>9 Bates number of that, please.</p> <p>10 MR. GASTEL: MNK-TNSTA --</p> <p>11 sorry. MNK-TNSTA04824847.</p> <p>12 QUESTIONS BY MR. GASTEL:</p> <p>13 Q. Do you recall receiving this</p> <p>14 e-mail, sir?</p> <p>15 A. No.</p> <p>16 Q. The e-mail starts with an</p> <p>17 e-mail from Karen Harper on January 18th,</p> <p>18 2017, to a variety of people. You're not on</p> <p>19 that e-mail. But it's inviting folks to join</p> <p>20 a conference meeting related to this attached</p> <p>21 press release.</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. And then the press release</p> <p>25 apparently comes from the DEA Public Affairs</p>
<p>1 when you left the company?</p> <p>2 A. No.</p> <p>3 Q. Who was in that role when you</p> <p>4 left the company?</p> <p>5 A. Amy Martinez.</p> <p>6 Q. Are you aware that in or around</p> <p>7 2007, McKesson had their license suspended by</p> <p>8 the DEA in certain of its operations because</p> <p>9 of McKesson's failure to maintain effective</p> <p>10 controls against diversion?</p> <p>11 A. No, I don't recall that. Also,</p> <p>12 in 2007, I didn't really work with --</p> <p>13 Q. Sorry. If I said 2007, I meant</p> <p>14 2017.</p> <p>15 A. Oh. Well, also in 2017, after</p> <p>16 March of 2017, I didn't really do anything</p> <p>17 with pharmaceuticals anymore. So, no, I was</p> <p>18 not aware of that.</p> <p>19 (Mallinckrodt-Saffold</p> <p>20 Exhibit 40 was marked for</p> <p>21 identification.)</p> <p>22 QUESTIONS BY MR. GASTEL:</p> <p>23 Q. I'll show you a document that's</p> <p>24 been marked as Exhibit 40. And this is an</p> <p>25 e-mail from Emily Breneman to you, Amy</p>	<p>1 Division.</p> <p>2 Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. And it's titled McKesson agrees</p> <p>5 to pay record \$150 million settlement for</p> <p>6 failure to report suspicious orders of</p> <p>7 pharmaceutical drugs.</p> <p>8 Did I read that correctly?</p> <p>9 A. Yes.</p> <p>10 Q. And it's dated January 17th,</p> <p>11 right?</p> <p>12 A. Yes.</p> <p>13 Q. Which would have been, I</p> <p>14 believe, one day before the January 18th,</p> <p>15 2017 e-mail that Karen starts this e-mail</p> <p>16 chain with.</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. And the press release states:</p> <p>20 McKesson Corporation, one of the nation's</p> <p>21 largest distributors of pharmaceutical drugs,</p> <p>22 agreed to pay a record \$150 million civil</p> <p>23 penalty for alleged violations of the</p> <p>24 Controlled Substances Act, the U.S. Drug</p> <p>25 Enforcement Administration announced today.</p>

Page 234	Page 236
<p>1 Did I read that correctly?</p> <p>2 A. Yes.</p> <p>3 Q. "The nationwide settlement</p> <p>4 requires McKesson to suspend sales of</p> <p>5 controlled substances from its distribution</p> <p>6 centers in Colorado, Ohio, Michigan and</p> <p>7 Florida for multiple years. The staged</p> <p>8 suspensions are among the most severe</p> <p>9 sanctions ever agreed to by a DEA-registered</p> <p>10 distributor. The settlement also imposes new</p> <p>11 and enhanced compliance obligations on</p> <p>12 McKesson's distribution system."</p> <p>13 Did I read that correctly?</p> <p>14 A. Yes.</p> <p>15 Q. Does this refresh your</p> <p>16 recollection at all about McKesson having</p> <p>17 some of its controlled substances licenses</p> <p>18 suspended by the DEA?</p> <p>19 A. I really don't remember this.</p> <p>20 Q. If you flip to the next page,</p> <p>21 which I think is the last page, at the very</p> <p>22 top it says: The government's</p> <p>23 investigation -- I'm sorry.</p> <p>24 A. Let me find it. Okay.</p> <p>25 Q. Maybe it's not the last page.</p>	<p>1 its failure to comply with the Controlled</p> <p>2 Substances Act, correct?</p> <p>3 A. Yes.</p> <p>4 Q. And then going back to the</p> <p>5 e-mail that you're copied on, it says: Let</p> <p>6 me know if you need any help from me with the</p> <p>7 item restrictions for Lakeland. Thanks,</p> <p>8 Emily.</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And then again, the e-mail</p> <p>12 below that shows the Aurora, Colorado and</p> <p>13 Livonia, Michigan accounts having their</p> <p>14 schedule drugs removed today.</p> <p>15 Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. And that would be January 20th,</p> <p>18 2017, right?</p> <p>19 A. Yes.</p> <p>20 Q. And I assume that customer</p> <p>21 service would have to get involved in this in</p> <p>22 order to essentially flip off the switch to</p> <p>23 allow orders of Mallinckrodt controlled</p> <p>24 substances to go to these locations that</p> <p>25 McKesson no longer had a DEA license for,</p>
Page 235	Page 237
<p>1 I'm sorry. Are you with me?</p> <p>2 A. Yes.</p> <p>3 Q. It says: The government's</p> <p>4 investigation developed evidence that even</p> <p>5 after designing a compliance program after</p> <p>6 the 2008 settlement, McKesson did not fully</p> <p>7 implement or adhere to its own program. In</p> <p>8 Colorado, for example, McKesson processed</p> <p>9 more than 1.6 million orders for controlled</p> <p>10 substances from June 2008 through May 2013,</p> <p>11 but reported just 16 orders as suspicious,</p> <p>12 all connected to one instance related to a</p> <p>13 recently terminated customer.</p> <p>14 Did I read that correctly?</p> <p>15 A. Yes.</p> <p>16 Q. And that reference to the 2008</p> <p>17 settlement, we saw in a previous PowerPoint,</p> <p>18 Mallinckrodt was aware of based on that</p> <p>19 executive committee presentation of April</p> <p>20 2011.</p> <p>21 Do you recall that?</p> <p>22 A. Yes.</p> <p>23 Q. And then here's another</p> <p>24 instance of McKesson being -- having an</p> <p>25 enforcement action undertaken by the DEA for</p>	<p>1 right?</p> <p>2 A. Well, you know, I'm not so</p> <p>3 sure, to flip the switch. That's owned by</p> <p>4 data integrity analysts and data integrity</p> <p>5 department, so I think maybe even -- so I</p> <p>6 don't think we would.</p> <p>7 And then Emily reports --</p> <p>8 reported to me in customer service, and I</p> <p>9 think she's asking here, hey, do you need us</p> <p>10 to, but I don't think we had to do much to</p> <p>11 remove a schedule. I don't think we owned</p> <p>12 that, that switch.</p> <p>13 Q. And I'm sorry, in your opinion,</p> <p>14 who owned that switch?</p> <p>15 A. Data integrity.</p> <p>16 Q. And who did they report to?</p> <p>17 A. I don't know who data integrity</p> <p>18 rolled up into. I think they were kind of</p> <p>19 part of the finance org, but -- and I can't</p> <p>20 recall the name of who kind of owned that</p> <p>21 group.</p> <p>22 Q. Do you know if any of</p> <p>23 Mallinckrodt's shipments to these McKesson</p> <p>24 facilities that had their license suspended</p> <p>25 by the DEA were flagged by Mallinckrodt's</p>

Page 238	Page 240
<p>1 algorithm as potentially -- or as peculiar 2 orders?</p> <p>3 MR. BERG: Objection. Object 4 to form.</p> <p>5 A. I don't know.</p> <p>6 QUESTIONS BY MR. GASTEL:</p> <p>7 Q. Do you know if Mallinckrodt 8 reported any of these -- any of its previous 9 orders to these McKesson distribution 10 facilities that had their licenses suspended 11 by the DEA, did Mallinckrodt report that -- 12 any of those orders to the DEA as suspicious?</p> <p>13 A. I don't know.</p> <p>14 Q. And you would ask Karen Harper 15 those questions if you needed to know that?</p> <p>16 A. Yes.</p> <p>17 Q. Did it ever concern you that 18 Mallinckrodt's distribution customers were 19 getting into trouble with the DEA and -- 20 well, strike that.</p> <p>21 Did it ever concern you that 22 Mallinckrodt's distribution customers were 23 getting in trouble with the DEA?</p> <p>24 MR. BERG: Object to form.</p> <p>25 A. Yes.</p>	<p>1 QUESTIONS BY MR. GASTEL:</p> <p>2 Q. Do you recall if there was ever 3 an attempt to make adjustments to the 4 algorithm to reflect that Mallinckrodt's 5 distribution customers were getting in 6 trouble with the DEA?</p> <p>7 MR. BERG: Object to form.</p> <p>8 A. I don't really recall any. (Mallinckrodt-Saffold 10 Exhibit 41 was marked for 11 identification.)</p> <p>12 QUESTIONS BY MR. GASTEL:</p> <p>13 Q. I'm going to hand you a 14 document that we'll mark as Exhibit 41. And 15 this is an October 28, 2013 e-mail from Amy 16 Martinez to you titled Materials. 17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 MR. GASTEL: And the Bates 20 number on it --</p> <p>21 MR. MILLER: Bates number on 22 the document? Ah, thank you.</p> <p>23 MR. GASTEL: -- is 24 MNK-T1_0007872732. 25 --oOo--</p>
<p>1 QUESTIONS BY MR. GASTEL:</p> <p>2 Q. Did you ever bring that up in 3 any of the meetings that you had with the 4 Suspicious Order Monitoring steering 5 committee?</p> <p>6 A. No.</p> <p>7 Q. Do you ever recall it being 8 discussed?</p> <p>9 MR. BERG: Object to form.</p> <p>10 A. Yes. We're, at Mallinckrodt, 11 certainly our compliance team, they really 12 discussed, you know, hey, here's -- you know, 13 as you see in slides, I think it's evident, 14 the team likes to -- you know, chose to 15 discuss these actions because we want to make 16 people -- I think the intention was to raise 17 awareness of the importance of compliance.</p> <p>18 QUESTIONS BY MR. GASTEL:</p> <p>19 Q. Was there ever a discussion 20 retroactively to look back to see if the 21 algorithm was correctly flagging any of the 22 orders that the DEA was later penalizing 23 Mallinckrodt's distributors for?</p> <p>24 MR. BERG: Object to form.</p> <p>25 A. I don't recall any.</p>	<p>1 QUESTIONS BY MR. GASTEL:</p> <p>2 Q. And the body of the e-mail 3 says: Hi George. I meet -- and I think she 4 means met -- I met this morning with Ginger. 5 I will be scheduling some time to sit with 6 her to learn a little more about the generics 7 part of our business. Attached are some 8 resources that she shared. Amy. 9 Did I read that correctly?</p> <p>10 A. Yes.</p> <p>11 Q. Do you recall this e-mail?</p> <p>12 A. No.</p> <p>13 Q. Do you recall the Ginger that 14 she's referencing?</p> <p>15 A. Yes.</p> <p>16 Q. And do you know why Amy would 17 have been sending her training materials for 18 the generic part of the business?</p> <p>19 A. Oh, no, I'm sorry. I think 20 Ginger sent Amy these materials.</p> <p>21 Q. Got it. And then Amy was being 22 trained on the generic part of the business?</p> <p>23 A. Yes.</p> <p>24 Q. I'm sorry, I did flip those 25 around.</p>

Page 242	Page 244
<p>1 And then Amy was forwarding 2 them on to you? 3 A. Yes. 4 Q. To make you aware that she had 5 been trained on these materials? 6 A. Yes. 7 Q. And then do you recall why you 8 asked her to be trained on these materials? 9 MR. BERG: Object to form. 10 A. So I didn't ask her to be 11 trained on these materials. I did ask her to 12 make sure she understood the generics 13 business. She was coming from the API 14 business and I wanted to make sure she had a 15 successful onboarding with responsibilities 16 for generics.</p> <p>17 QUESTIONS BY MR. GASTEL:</p> <p>18 Q. And why is that? 19 A. Because she was becoming the -- 20 we're changing her role, so she was replacing 21 Kris as the manager of both generics and API.</p> <p>22 Q. And do you see that the e-mail 23 attaches various PowerPoint presentations and 24 training materials?</p> <p>25 A. Yes.</p>	<p>1 Do you see that? 2 A. Yes. 3 Q. And the source of this material 4 was apparently IMS Health pharmaceutical 5 data.</p> <p>6 Do you see that? 7 A. Well, it looks like there are 8 several sources.</p> <p>9 Q. Sure.</p> <p>10 A. IMS Health, PhRMA, AC Nielsen, 11 the FDA and then a few others as well.</p> <p>12 Q. Sure.</p> <p>13 And then on the next page, 14 there's a chart?</p> <p>15 A. Yes.</p> <p>16 Q. And it says Key Competitors for 17 Mallinckrodt Products.</p> <p>18 Do you see that? 19 A. Yes.</p> <p>20 Q. And Actavis is listed having 21 apparently \$2.3 billion in sales.</p> <p>22 Do you see that? 23 A. Yes.</p> <p>24 Q. And then Mallinckrodt is next 25 with \$770 million in sales.</p>
<p>1 Q. And the first PowerPoint 2 presentation is entitled Mallinckrodt 3 Pharmaceuticals Specialty Generics Overview, 4 10/13. I think it's the first page after the 5 e-mail.</p> <p>6 A. Yes.</p> <p>7 Q. Do you see that? 8 A. I do.</p> <p>9 Q. Will you flip to -- 10 unfortunately, the pages aren't marked, but 11 will you flip to the graph that has Proposed 12 Generic Total Market Sales?</p> <p>13 A. Yes. I think I'm there. Okay, 14 I'm there.</p> <p>15 Q. It says Projected Generic Total 16 Market Sales in billions of dollars.</p> <p>17 Do you see that? 18 A. Yes.</p> <p>19 Q. And then there's a chart here 20 that shows that in 2008, the generic market 21 was approximately \$60 billion?</p> <p>22 Do you see that? 23 A. In 2008, yes.</p> <p>24 Q. And then in 2016, it was 25 projected to grow to \$100 billion.</p>	<p>1 Do you see that? 2 A. Yes. 3 Q. And the source of this material 4 was IMS?</p> <p>5 MR. BERG: Object to form.</p> <p>6 QUESTIONS BY MR. GASTEL:</p> <p>7 Q. Do you see that? 8 A. Yes.</p> <p>9 Q. And then if you will flip to -- 10 maybe there are page numbers. Page 11? 11 A. Oh, got it.</p> <p>12 Q. And it says Products Driving 13 Net Sales.</p> <p>14 Do you see that? 15 A. Yes.</p> <p>16 Q. And it says in millions.</p> <p>17 Do you see that? 18 A. Yes.</p> <p>19 Q. And it's a pie graph.</p> <p>20 Do you see the pie graph? 21 A. Yes.</p> <p>22 Q. And in the upper right-hand 23 corner, there is a section of the pie that 24 says Methylphenidate.</p> <p> Do you see that?</p>

Page 246	Page 248
1 A. Yes.	1 (Deposition recessed at
2 Q. And that is apparently the	2 3:50 p.m.)
3 largest net sale here, correct?	3 --oOo--
4 A. Yes.	4
5 Q. And are these Mallinckrodt	5
6 generic products?	6
7 MR. BERG: Object to form.	7
8 A. Yes. Well, I don't know.	8
9 These are all products Mallinckrodt sold,	9
10 yes.	10
11 QUESTIONS BY MR. GASTEL:	11
12 Q. That's what I mean.	12
13 A. But I don't know if this is	13
14 exclusive to Mallinckrodt, no.	14
15 Q. Sure.	15
16 And then hydrocodone at	16
17 120 million is the next largest chunk of the	17
18 pie?	18
19 A. Yes.	19
20 Q. And oxycodone/oxycodone APAP is	20
21 the next largest chunk?	21
22 A. Yes.	22
23 Q. Right? And the fentanyl patch	23
24 is the next largest chunk?	24
25 A. Yes.	25
Page 247	Page 249
1 Q. And then the morphine ER is the	1 CERTIFICATE
2 next largest chunk.	2 I, SUSAN PERRY MILLER, Registered
3 Do you see that?	3 Diplomate Reporter, Certified Realtime
4 A. Yes.	4 Reporter, Certified Court Reporter and Notary
5 Q. And those last four, those are	5 Public, do hereby certify that prior to the
6 all opioids, right?	6 commencement of the examination, GEORGE
7 A. Yes.	7 SAFFOLD was duly sworn by me to testify to
8 Q. Was it your understanding in	8 the truth, the whole truth and nothing but
9 your time at Mallinckrodt that Mallinckrodt	9 the truth;
10 generic opioids were approximately half or	10
11 more than half of the net sales for generic	11 That pursuant to Rule 30 of the
12 products at Mallinckrodt?	12 Federal Rules of Civil Procedure, signature
13 A. Yes.	13 of the witness was not reserved by the
14 MR. GASTEL: Mr. Saffold, I'm	14 witness or other party before the conclusion
15 sure this will be music to your ears,	15 of the deposition;
16 but that's all the questions I have	16
17 for you, subject to my earlier	17 That the foregoing is a verbatim
18 objection. We'll reserve the right,	18 transcript of the testimony as taken
19 but that's all I have for you today.	19 stenographically by and before me at the
20 THE WITNESS: Okay. Thank you.	20 time, place and on the date hereinbefore set
21 THE REPORTER: Anything	21 forth, to the best of my ability.
22 further?	22
23 MR. BERG: No questions.	23 I DO FURTHER CERTIFY that I am
24 THE VIDEOGRAPHER: Off the	24 neither a relative nor employee nor attorney
25 record at 3:50.	25 nor counsel of any of the parties to this
	26 action, and that I am neither a relative nor
	27 employee of such attorney or counsel, and
	28 that I am not financially interested in the
	29 action.
	30
	31 Susan Perry Miller
	32 CSR-TX, CCR-LA, CSR-CA-13648
	33 Registered Diplomate Reporter
	34 Certified Realtime Reporter
	35 Certified Realtime Captioner
	36 NCRA Realtime Systems Administrator
	37 Notary Public, State of Texas
	38 My Commission Expires 03/30/2020
	39 Dated: 12th of February, 2019

Page 250

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LAWYER'S NOTES

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